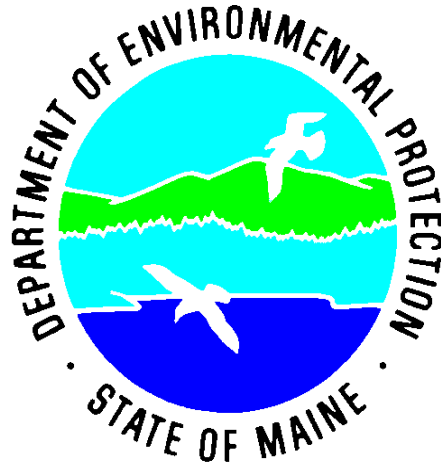


**Maine Department of Environmental Protection
Quality Management Plan**



**Approved Revision No. 2
June, 2003**

**Maine Department of Environmental Protection
#17 State House Station
Augusta, Maine 04333-0017**

**Quality Management Plan
Maine Department of Environmental Protection**

Approvals:

- 1) Name: Dawn H. Gallagher
Title: Commissioner, Maine Department of Environmental Protection

Signature: _____ Date: _____

- 2) Name: Malcolm C. Burson
Title: Quality Assurance Manager, Maine Department of Environmental Protection

Signature: _____ Date: _____

- 3) Name: Gerry Sotolongo
Title: Regional Quality Assurance Manager, EPA Region I

Signature: _____ Date: _____

- 4) Name: Stephen Silva
Title: EPA Maine State Director

Signature: _____ Date: _____

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LIST OF ACRONYMS

<u>Word</u>	<u>Acronym</u>
American National Standard / American Society for Quality (formerly ASQC)	ANSI/ASQ
Agency Technology Officer	ATO
Bureau of Air Quality	BAQ
Bureau of Human Resources	BHR
Bureau of Land and Water Quality	BLWQ
Bureau of Remediation and Waste Management	BRWM
Computer Services Unit	CSU
Data Quality Indicator	DQI
Data Quality Objective	DQO
Data Management Unit	DMU
Environmental Protection Agency	EPA
Information Systems Steering Committee	ISSC
International Standards Organization	ISO
Geographic Information System	GIS
Global Positioning System	GPS
Local Area Network	LAN
Leaking Underground Storage Tanks	LUST
Maine	ME
Maine Department of Environmental Protection	Maine DEP
Maine Revised Statutes Annotated	M.R.S.A.

National Pollutant Discharge Elimination System	NPDES
Office of the Commissioner	OC
Performance Partnership Agreement	PPA
Quality Assurance Manager	QAM
Quality Assurance / Quality Control / Quality Improvement	QA/QC/QI
Quality Assurance Project Plan	QAPP
Quality Control	QC
Quality Management Plan	QMP
Quality Management System	QMS
Quality Management Steering Committee	QMSC
Request for Proposal	RFP
Resource Conservation Recovery Act	RCRA
Response for Requested Action	RFRA
Sampling and Analysis Plan	SAP
Standard Operating Procedure	SOP
Toxic Substances Control Act	TSCA
Wide Area Network	WAN

1.0 MANAGEMENT AND ORGANIZATION

Maine's Legislature established the Department of Environmental Protection (Maine DEP) as the State's administrative agency in charge of controlling the release of pollution generated by its citizens and protecting and enhancing its natural environment. Maine DEP is organized and managed to accomplish these tasks in an efficient and effective manner. High quality is of primary importance in all aspects of Maine DEP's operations.

1.1 Maine Department of Environmental Protection (Maine DEP) Mission

Maine law establishes that the Maine DEP:

"...shall prevent, abate and control the pollution of the air, water and land and preserve, improve and prevent diminution of the natural environment of the State. [DEP] ...shall protect and enhance the public's right to use and enjoy the State's natural resources and may educate the public on natural resource use, requirements and issues." 38 M.R.S.A. § 341-A(1).

1.2 Maine DEP Management

Pursuant to the authority vested in the commissioner, the agency is divided into three (3) programmatic units referred to as *bureaus*: Bureau of Air Quality (BAQ); Bureau of Land and Water Quality (BLWQ); and Bureau of Remediation and Waste Management (BRWM). Additional functions are carried out by staff in the Office of the Commissioner (OC), and by the ACE Service Center for some financial and personnel responsibilities. By law, the Maine DEP's top manager is its *Commissioner*. Day-to-day operations of the agency as a whole and direct management of the OC are overseen by the *Deputy Commissioner* position. Each bureau has a top manager, referred to as *bureau director*, who reports directly to the Commissioner. Each bureau is further divided into divisions, each of which is managed by a *division director*. Each division is further divided into functional and programmatic units that are managed by *unit managers*. These management relationships are illustrated in Appendix 1. The individuals holding each of these management positions are fully authorized to direct the actions of their staff within the scope of the staff member's employment.

The functions of the Department are carried out in four regions of the State from the primary Department offices in Augusta, and from regional offices in Bangor (Eastern), Presque Isle (Northern), and Portland (Southern). Each office is managed by a Regional Director, who is outside the bureau management structure of the programs. Directors represent the Commissioner (to whom they report) in the regions, address matters of Departmental interest where more than one program area may be involved, and represent the Department in inter-agency matters.

1.3 Quality Assurance, Quality Control, and Quality Improvement (QA/QC/QI) Policy

The Maine DEP seeks to maintain the highest appropriate standard of quality in each aspect of its operations in order to meet its obligation to protect Maine's natural

environment and the health of Maine citizens. To this end, Maine DEP operates under a Quality Management System (QMS). As part of its QMS, this Quality Management Plan (QMP) provides the guidance Maine DEP uses to establish and maintain consistent and appropriate QA/QC/QI operations agency-wide. This QMP is consistent with ANSI/ASQC-E4 (1994), ISO 9000: 2000 and EPA QA/R-2 (2001). The Maine DEP QA/QC/QI policy statement is attached to this QMP at Appendix 2.

The individuals served by the implementation of Maine DEP's QMP and all other resulting quality efforts include: our agency's staff; Maine citizens; non-governmental interest groups; federal, state and local government administrative agencies; and, Congress and the Maine State Legislature. Maine DEP is committed to serving these customers with the highest appropriate standard of quality in our services.

1.4 Management Responsibility for QA/QC/QI Functions

All managers are responsible for maintaining QA/QC/QI for the area within their span of control. As such, commitment to and responsibility for the quality objectives and operations detailed in this QMP and any Quality Assurance Project Plan (QAPP) or Standard Operating Procedure (SOP) in place at Maine DEP begins with the commissioner and continues through all levels of management and staff. The State's Performance Management Plan for managers includes performance standards consistent with this Quality Management Plan, which provides guidance for implementation. Likewise, managers should include appropriate responsibility for maintaining QA/QC/QI in the performance expectations and review of their staff.

The Maine DEP's ongoing implementation of its QMS uses the auditing regime established in Element Nine of this QMP to annually target areas of interest identified by the agency's Quality Management Steering Committee (QMSC) for improvement.. Managers assure that Corrective Action Requests and Plans resulting from such audits are responded to and implemented in a timely manner by supervisors and employees in their units (see 9.9).

2.0 QUALITY MANAGEMENT SYSTEM COMPONENTS

The Maine DEP views its QMS as encompassing, and applicable to, all aspects of its operations. The QMS is particularly applicable to environmental data operations, a list of which can be found in Appendix 8. To accomplish this holistic approach to ensuring quality, the Maine DEP has adopted a practical approach to QA/QC/QI functions that includes this QMP as the guidance for implementing its QMS. QA/QC/QI functions are carried out by personnel throughout the Maine DEP who, pursuant to the provisions contained throughout this QMP, are fully informed of and trained in their quality related responsibilities. The quality controls promulgated by Maine DEP – QMP, QAPPs, and SOPs – are applied as necessary after Quality Objectives (QO) commensurate with project needs have been defined. Each program area in the Maine DEP is responsible for establishing, documenting, implementing, and reviewing QA/QC and quality management procedures germane to its area of operations.

2.1 QA/QC/QI Staff

The Maine DEP organizes and oversees agency-wide QA/QC/QI functions with a Quality Management Steering Committee (QMSC). Six (6) management-level individuals comprise the QMSC, with at least one (1) representative being from each bureau and one (1) member being from senior management. The QMSC meets at least monthly to review quality issues and initiatives. Oversight of QMS activities by the QMSC assures that quality issues are integrated throughout the Maine DEP and that all levels of our management are consistently apprised of and accessible to take action on such issues.

Maine DEP's Quality Assurance Manager (QAM) is the individual serving as chair of the QMSC. The QAM convenes the QMSC; serves as Maine DEP's designated QA/QC/QI contact with EPA; and coordinates agency-wide activities with designated Quality Management Coordinators in each bureau. Those contacts may differ from the bureau representative serving on the QMSC. Appendix 6 identifies QA/QC/QI management responsibilities.

Each Maine DEP employee is responsible for planning the work that is done, documenting all work, and ensuring that the quality of work completed meets or exceeds the Quality Objectives (QOs) for the activity. Managers will work collaboratively with staff to ensure that decisions made when performing assigned tasks or making policy for the Maine DEP are based on quality.

2.2 QA/QC/QI Objectives

The quality demands of a specific program function or project should be defined prior to undertaking activities when a Quality Assurance Project Plan (QAPP) or Standard Operation Procedure (SOP) will be developed. By defining the Quality Objectives (QOs) of a function or project prior to taking action, the Maine DEP believes its processes will operate as efficiently and effectively as possible while at the same time creating results that are appropriately informative, and legally and technically defensible as accurate.

2.3 Quality Management Tools

2.3.1 Quality Management Plan (QMP)

This QMP is the guidance Maine DEP uses to design, document, and implement its QMS. The QMS includes the process of planning, implementing, and assessing QA/QC/QI operations. The Commissioner and Senior Management Team review and approve this QMP at the time of its original composition, and designate the QMSC to review and approve subsequent changes. This QMP will be renewed every five years or when significant changes have been made to its program elements, whichever comes first. The QMSC annually evaluates this QMP as part of its regular functions. This review and any recommendations resulting therefrom will be primarily based on findings made while implementing the auditing regime described in Element Nine of this QMP.

2.3.2 Quality Assurance Project Plans (QAPPs)

QAPPs are project specific plans that establish the method by which QOs will be met or exceeded. QAPPs are typically needed where significant data collection and analysis will be associated with a project. A QAPP dictates the minimum requirements for project management, data measurement, data acquisition, assessment, oversight, data validation and data usability. The QAPP should include the main elements listed in the document "*EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (EPA QA/R-5)*" (March, 2001)). Additional guidance for writing the QAPP can be obtained from the EPA documents "*EPA Guidance for Quality Assurance Project Plans*" (EPA QA/G-5) (July 1998), and "*Region 1, EPA-New England Compendium of Quality Assurance Project Plan Requirements and Guidance*" (October 1999). Each monitoring project or program will go through the Data Quality Objective (DQO) process outlined in the document "*Guidance for the Data Quality Objectives Process (EPA QA/G-4)*" (August, 2000). QAPP use, development, and requirements are detailed in Element Seven of the QMP.

2.3.3 Standard Operating Procedures

An activity that is performed regularly and requires uniform conduct each time it is performed should have a standard accepted methodology documented in a written SOP. Details on Maine DEP's SOP development, preparation, content, format, review, approval, release, revision, archival, and procedure withdrawal are contained in Element Eight of this QMP.

2.3.4 Guidance Documents

Information compiled to inform staff or other individuals of legal requirements, SOPs, or QAPPs may be contained in a written guidance document. Such

documents do not create new SOPs or legal requirements. An example of a guidance document is the compilation of legal memoranda, statutory language, and regulatory provisions compiled by Maine DEP's wastewater discharge program to assist its licensors with carrying out their day-to-day functions.

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

3.1 Commitment to Quality Assurance Training

All Maine DEP employees receive training, and participate in professional development, pertinent to their responsibilities and work assignments. Maine DEP provides, or arranges for, training specific to QA/QC/QI as needs are identified by the QMSC on the basis of audit results, management review, and/or information received from Bureau quality coordinators.

3.2 Qualifications

The Maine Department of Administrative and Financial Services, Bureau of Human Resources determines and maintains the classification system for positions needed by the Maine DEP. Each classification is defined by a minimum set of requirements including experience, education, and/or certification. Personnel hired by the Maine DEP must meet these minimum requirements to qualify for a certain position. The Maine DEP Personnel Officer is responsible for review of job classifications and for arranging audits of existing positions as requested, to ensure employees are classified correctly. The Personnel Officer also maintains position descriptions specifying the general and quality assurance knowledge and skill required for job tasks.

Specific types of work, or specific projects, require specific skills. Project Managers, supervisors and managers identify skill needs. If possible, skill needs are met by existing staff. If no DEP employee with the necessary skills is available to perform a specific type of work, management identifies the necessary resources, and initiates the procedures to hire or contract for the needed skills.

3.3 Professional Development and Training

Management identifies needs at the Maine DEP for professional development, learning new techniques, and qualifying for / maintaining required certifications (*e.g.*, 40 hour Occupational Safety and Health Administration training). Agency policy (Policy OC-PD-01, Professional Development, revision 1, 12/02) encourages staff to seek advanced degrees or professional training as needed to ensure that the Maine DEP mission is fulfilled and its objectives met. Maine DEP employees regularly are sponsored to, and participate in, regional and national professional conferences and workshops relevant to their job responsibilities. The State Performance Management System documentation requires the identification of individual development objectives at the beginning of each employee year, and the accomplishment of these objectives is a part of performance review. These expectations are developed through discussion between the employee and supervisor, and should reflect the identification of knowledge, skills, and competencies to be developed through training and professional development. They should also reflect the Department's, Bureau's, and program area's needs and goals, as reflected in planning documents such as annual division training plans or operational workplans.

The DEP has a Director of Professional Development responsible for identifying training needs, planning and implementing in-house training, and assisting employees in planning professional development. In addition, each Bureau and Regional Office designates an employee to serve as professional development liaison to the Director of Professional Development. The BRWM and Computer Services units have designated positions to deliver training programs to the Department. The State Bureau of Human Resources provides a wide range of learning opportunities useful to Maine DEP employees.

All internal classes are based on pre-defined learning objectives documented in the professional development/training management system. Training and professional development activities, both internal and external, including those related to QA/QC/QI, are tracked, and individual training records kept (beginning 2003) in the BHR-managed electronic training management system, which includes Maine DEP-designated competencies, maintenance of certifications, etc.

All Maine DEP employees are trained in the following areas:

- State and Maine DEP Orientation;
- Core training for managers and supervisors;
- Computer software;
- Sexual harassment;
- Customer service;
- Job-required safety and health; and
- Defensive driving when applicable.

Each Bureau, division, and program provides, and documents the provision of, additional training as needed to ensure that new staff members understand and can carry out job requirements to meet identified levels of competency. Resources for training and professional development are allocated at the Bureau level, based on program-specific funding streams.

Assessment of the status and adequacy of existing training and professional development programs, and identification of future training needs, is made annually as part of Maine DEP's Strategic Planning, Performance Budgeting, and Performance Partnership Agreement processes, and/or in available bureau, division, and program work plans. The Director of Professional Development reports the status of professional development and training annually to the Senior Management Team .

3.4 Training for Quality

All Maine DEP employees are required to be familiar with this QMP. Division and/or program managers annually review the QMP with staff, including specific aspects pertaining to the work of that unit.

All data-related programs requiring QAPPs have, within those documents, standards and procedures for assuring that program staff receive training in QA/QC related to their activities, and maintain proficiency in the QA/QC requirements of that program. In other

programs and activities, supervisors and program managers are responsible for assuring such training. Individual programs conduct workshops and training activities specific to their needs to assure quality, test employee proficiency, etc.

Maine DEP provides training that specifically enables staff to carry out the auditing functions described in 9.0, and assures that staff maintain necessary qualifications and proficiency.

4.0 PROCUREMENT OF ITEMS AND SERVICES

Maine DEP procures a variety of commodities and services generally, and specifically for environmental data collection needs, through various vendors, including laboratories and technical firms. The procurement of items and services will be controlled and documented to assure conformance with specified quality management requirements. These requirements will be included or referenced in procurement documents. The acceptability of purchased items and services will be verified and documented by the individual who has requested the goods or services.

The Division of Purchases within the Department of Administrative and Financial Services establishes the broad framework for the purchase of goods and services within Maine state government. The Maine DEP conducts its purchasing practices in accordance with all requirements of the Division of Purchases.

Procurement within the Maine DEP is conducted by designated personnel in each of the three program bureaus and in the Office of the Commissioner.

4.1 Documents

All procurements are defined in writing in one or more procurement documents (purchase requisitions, requests for proposals, procurement contracts, and other agreement documents). Routine commodity purchases are made through the use of a purchase requisition. A Request for Proposal (RFP) is sometimes developed for procurement of services and stipulates requirements of Maine DEP. The nature of the work, the location, and the anticipated cost are factors that contribute to the determination of when an RFP is necessary. Quality assurance requirements of all potential contractors are clearly identified within the RFP and are a requirement of all contract documents. Program managers determine such quality assurance requirements, with the assistance of quality assurance staff. An RFP has a set of screening criteria that ensure the potential contractors meet the quality requirements. A designated group is responsible for review of proposals, for scoring the proposals by preset criteria, and for selecting the contractor(s). Occasionally, a bidders' conference is scheduled to address any questions which bidders may have. The Maine DEP notifies the successful contractor(s) and contracts are established.

Quality assurance of analytical work conducted by a laboratory is determined, in part, through the State of Maine Department of Human Services (Maine DHS) laboratory certification program, as private laboratories may apply to the Maine DHS for certification. In cases when requests for services are outside of the scope of certification program standards, Maine DEP staff will establish quality assurance guidelines in accordance with Department standards. The laboratory must meet these guidelines to be considered for work by Maine DEP. See also 7.5, 9.1.

The Department is working with the Division of Purchases to develop commodity-specific requirements to assure that the quality of items and services provided to our suppliers by their suppliers is ensured.

Procurement documents may include pre- and post-award source inspections, supplier audits, readiness reviews, evaluations of objective evidence of quality furnished by the supplier, acceptance testing, and other requirements as determined by program managers to be appropriate.

Procurement of services through financial assistance agreements for environmental programs follows the same general guidelines, whether or not the procurement uses a formal RFP process. Agreements specify the services to be delivered. Program managers are responsible for developing and documenting procedures to review such agreements for quality considerations, including documentation of a recipient's quality system. See Appendix 8 for examples of such programs.

4.2 Acceptance of Items and Services

Items and services affecting quality received from suppliers are evaluated upon delivery against acceptance criteria (task and product specifications and technical, quality, administration and other requirements) contained in procurement documents. Program managers, or their designates, determine whether acceptance criteria have been met and whether items and services are adequate and appropriate for use. This standard applies to work carried out by sub-contractors engaged in remediation and other environmental operations under the terms of a DEP contract.

Items and services that do not meet acceptance criteria are not accepted for use. Corrective actions are initiated in accordance with state requirements, contract provisions, and procurement procedures. Corrective actions may range from repair or replacement of defective deliverables to return of unacceptable items or refusal of payment for goods or services rendered.

The Division of Purchases coordinates resolution of disputes regarding quality through use of one of several methods available.

4.3 Grant Recipients

Several program areas in Maine DEP are responsible for allocating funds through grants to outside entities carrying out environmental operations. Activities carried out through the use of such grants are considered procurement of goods and services. DEP program managers are responsible for assuring that grant projects meet identified quality standards, including the development and approval of QAPPs for activities involving environmental data collection; and that grant recipients insure the quality of any operations conducted by their sub-contractors. This standard is included in all contracts between the DEP and grant recipients.

5.0 DOCUMENTS AND RECORDS

Each bureau and office at the Maine DEP is responsible for establishing and implementing procedures for controlling, filing, storing, protecting, and accessing documents and records in conformance with Maine DEP QMS / R-1, *Control of Department Documents and Records* (see Appendix 7).

5.1 Document and Record Development and Identification

Documents that specify quality-related requirements and instructions include:

- Maine DEP Quality Management Plan;
- program guidance documents;
- quality assurance project plans (QAPPs);
- technical standard operating procedures (SOPs);
- sampling and analysis plans (SAPs);
- data management plans;
- letters and correspondence; and
- internal Department and bureau policies

Program guidance documents are proposed, reviewed, and approved by staff and managers of relevant areas of the department. Revisions to guidance documents are made as necessary and reviewed in the same manner as new guidance documents. New guidance documents and revisions to existing guidance documents are uniquely identified. The Division Director or the management team of the respective bureau or office approves each new or revised guidance document, prior to issuance.

QAPPs are prepared, reviewed, approved, distributed, maintained and revised according to procedures described in 7.3.

Sampling and analysis plans (SAPs) and similar quality assurance plans are prepared, reviewed, approved, distributed, maintained and revised according to Maine DEP procedures described in 7.4.

SOPs (see 8.0) are proposed, reviewed, and approved by staff and managers of relevant areas of the department. Revisions to SOPs are made as necessary and reviewed in the same manner as new SOPs. New SOPs and revisions to existing SOPs are uniquely identified. The Division Director, the Bureau Director, or the Commissioner, depending on the scope of the SOP approves each new or revised SOP, prior to issuance. SOPs will conform to SOP OC-PE-001, "Standard Operating Procedure Development, Format, Approval and Distribution," Appendix 4 of this QMP, supplemented by applicable bureau guidance documents.

Department-level policies are reviewed and approved by the Senior Management Team prior to signature by the Commissioner. Originals are filed in the Office of the

Commissioner. Copies are distributed to all staff, and posted electronically on the Department's intranet site.

Quality assurance records are items that furnish objective evidence of the quality of items or activities that have been verified and authenticated as technically complete and correct. Quality assurance records may include photographs, drawings, forms, reports, and electronically recorded data.

Public records are records produced by Maine DEP and maintained as official records of the State (1 M.R.S.A § 402(3)). Public records are documented in the Records Retention Schedule (a State-generated document) for each bureau or office (5 M.R.S.A § 95(7)). Assignments of authority and procedures concerning the identification, verifications, authentication, handling, retention, and disposition of documents and records needed to safeguard the legal and financial rights of the state of Maine and any person directly affected by activities of the Maine DEP are contained in SOPs in each bureau.

Other quality assurance records are records that furnish objective evidence of the quality of items or activities but are not listed in the Records Retention Schedule. Written procedures have not been established to manage other quality assurance records; however there is an effective standard practice in place that is described below.

Documents and records received by Maine DEP from regulated entities, or as a part of extramural agreements involving the use of contractors or the recipients of financial assistance, are treated in the same manner as those generated internally in conformance with QMS R/1 (2001). When using documents created outside DEP, program managers assure that DEP staff use the most recent revision.

It is the responsibility of program managers and Division Directors to determine whether other records are required to reflect the achievement of required quality for completed work and to fulfill any statutory, regulatory, or contractual requirements for environmental programs. If such records are required, it is the responsibility of program managers and Division Directors to ensure these records are identified, verified, authenticated, handled, retained, and disposed of so that the records are accessible and protected from damage or deterioration. Project-specific quality assurance records are identified in quality assurance project plans (QAPPs).

The Quality Assurance Manager maintains quality assurance records relating to the Maine DEP quality system that are not otherwise identified in the Records Retention Schedule.

Program managers and Division Directors maintain quality assurance records relating to their respective programs that are not otherwise identified in the Records Retention Schedule.

Project managers maintain quality assurance records relating to their respective projects that are not otherwise identified in the Records Retention Schedule.

Each of these individuals specifies the location of and procedures for identifying, verifying, authenticating, handling, retaining and disposing of these records. These

individuals also keep a current listing of all types of quality assurance records that relate to their respective areas of responsibility.

5.2 Document and Record Storage

Document and record storage within each bureau or office is the responsibility of individuals charged with performing the tasks associated with this function. Some bureaus or offices have established controlled-access central file systems while others regulate storage to a lesser degree. The policies for each bureau or office are found in each record repository, and in the office of the bureau or regional director. All Maine DEP employees have access to Department files during normal business hours. So that we may assure availability of the requested information, members of the public are required to schedule an appointment to review Department files. All files will remain in the possession of the Department at all times.

Confidential documents are stored in secure areas within each bureau or office. Procedures for chain of custody and confidentiality for evidentiary documents and records are documented in all QAPPs, Sampling and Analysis Plans (SAPs), and other quality assurance plans.

File maintenance is the responsibility of all Maine DEP employees. Each division or program area, as appropriate, establishes documented protocols for file maintenance. Employees are required to file their own documents or have this task done by the documents and records managers according to regional policy.

Files are kept on-site within the Department or are in storage at the State Records Center or at the State Archives, according to the terms identified in the Record Retention Schedule for each bureau or office.

5.3 Archival Storage

Once files have been kept at the Department for the appropriate length of time, as defined in the Records Retention Schedule, they are sent to archival storage at the State Records Center or at the State Archives. When archiving documents and records, individuals designated with this responsibility follow a protocol established by the Records Center. Individuals assigned responsibility for documents and records management are required to maintain a record of the files that are being recalled from permanent storage at the State Records Center or at the State Archives.

5.4 Requests from the General Public

In the event that a member of the general public wishes to review Maine DEP files, individuals assigned the responsibility for documents and records management follow bureau-, program-, or office-specific procedures to assure availability of the requested material to the extent possible.

Documents and Records managers respond to written Freedom of Access Law requests in accordance with the requirements codified in that statute.

6.0 COMPUTER HARDWARE AND SOFTWARE

Information technology is critical to the performance of the mission of the Department of Environmental Protection. Computer systems are used to gather, store, analyze, retrieve, visualize, archive and publish data for use by Maine DEP staff, interested parties and the general public, and to support the administrative and operational activities of the Department. Computer software and hardware supporting all aspects of the Department's operations will be managed to ensure the safety, usability and accessibility of data of all sorts.

Equipment and systems covered under this section include:

- Desktop hardware and software used by Maine DEP staff and consultants
- Server hardware and software used to store and access environmental data, e-mail and documents
- Communications hardware and software used to interconnect desktop and server equipment including local area networks (LANs), wide area networks (WANs), the Internet and other remote networks

Systems are classified as to their level of support within the Department:

- Level 1 hardware and software is centrally developed or procured and supported by the Computer Services Unit staff
- Level 2 hardware and software is developed and supported by bureau Data Management Unit staff
- Level 3 hardware and software is developed or procured and supported by using program staff.

6.1 Development and Revision of Information Technology Standards

The Information Systems Steering Committee (ISSC) develops, reviews and revises agency technology standards for computer hardware and software to ensure that they meet the DQO's of Maine DEP programs and are consistent with the policies and standards promulgated by the Information Systems Policy Board of the State of Maine.

The Agency Technology Officer (ATO) ensures that technology standards are implemented in departmental systems.

Data Management Unit (DMU) managers ensure that technology standards are implemented in bureau level systems.

Maine DEP is currently developing and documenting the following technology standards:

- Maine DEP Standards for Level 1, Level 2 and Level 3 Information Technology systems
- Maine DEP Standards for desktop workstation configurations
- Maine DEP Technology Software Development Methodology
- Maine DEP Standards for Global Positioning Systems Data Gathering
- Maine DEP SOP for Computer Access Forms

- Maine DEP SOP for Preventing and Dealing with Computer Viruses
- Maine DEP SOP for System Backups

Once completed, these will be permanently available on a common network drive, and identified as “Information Systems Guidance Documents.” Maine DEP expects the series to be completed by 12/31/03.

6.2 Hardware

6.2.1 Office Automation (Desktop) Workstations

The standards for office automation workstations specify the minimum configuration sufficient to run the Department’s standard software and operate on the local area networks. Systems smaller than the minimum standard are replaced as financial resources allow.

The standards for new systems set forth specifications in sufficient detail to ensure that delivered systems will successfully run all Department-standard software and will work on local-area networks without modification. The Computer Services Unit tests examples of each configuration before large orders are placed. All such systems are purchased by the ATO following the same specifications, and are set up and installed by trained staff or contractors under the supervision of the ATO.

Users wishing to change the configuration of an installed system must first obtain the approval of their DMU. The DMU will evaluate the proposed change to ensure that the change will achieve the desired improvement and that no deterioration of service will result either for the system(s) involved or for other attached systems. Non-conforming purchases should be documented as exceptions or additions to the standard configurations.

6.2.2 Technical Workstations, Servers, and Network Components

The ATO reviews and approves specifications for the purchase of all levels of this equipment, giving consideration to the service requirements of each device being purchased and the current interface standards that will ensure it can play its role in the Department’s networked environment.

The equipment will be tested prior to being put into production to ensure that is capable of supporting the functionality and capacity required and that there are no adverse impacts on other system components.

Changes to the hardware and software configurations will be made by trained staffed who are authorized to carry out these functions. All configuration changes will be recorded in the device configuration log.

6.3 Software

6.3.1 Custom Developed Software

Level 1 and level 2 software are developed under a uniform software development methodology defined in “Maine DEP Software Development Methodology” to ensure that the software will meet the needs of the users and function properly in the Maine DEP network. Level 3 software development follows the general steps of the methodology and is inspected by ATO before being put into production.

Program staff that will use the software develop user requirements. Test plans are produced from the user requirements. All products of the software development process, including requirements, designs, code, test plans, and test results are inspected, and successful inspection is an exit criterion for each phase. Inspection teams document the defects found at each phase and record this information to be used as the basis for process improvements.

6.3.2 Off the Shelf Software

A standard suite of office software and other commonly used programs is specified by the ISSC in a manner consistent with standards set at the State level. Installation and configuration is carried out internally by the CSU staff. Other off the shelf software will be tested to ensure that it meets user needs and will function properly on the Maine DEP network.

6.3.3 User Training

User training is provided for all software to ensure that staff is able to use the software effectively. The Computer Services Unit provides training on Level 1 software. The party responsible for software support provides training and/or support on lower level software.

6.4 Data and Information

Responsibility for quality of data that is produced from or collected by computers lies with program staff. User requirements for developed or purchased systems identify the requirements for data quality and the inspection and testing procedures needed to ensure that the delivered system meets those requirements. Guidance documents (QAPPs, SOPs and other operational documents) set forth the procedures and means of managing data to ensure their quality during their useful life. The Information Services Steering Committee (ISSC) reviews operating plans and guidance documents to assure that data quality requirements are met.

6.4.1 Archiving Source Data

Operating plans for environmental programs address the needs and methods for archiving source documents according to the procedures set forth in Section 5

Documents and Records of this plan. Programs that receive electronically submitted data that needs to be archived will ensure that the receiving system creates an appropriate archival record of who submitted the data, when it was submitted along with a copy of the contents of the submission. Any software and media for archiving these data must be maintained and upgraded in such a manner that it is possible to retrieve and reproduce the archived records during their required archival period.

6.4.2 Safeguarding Current Data

Operating plans for programs that store data electronically address the needs and methods for safeguarding the data from loss and corruption during their useful life. This should include at a minimum a method for regular back up of data as set forth in section 6.5.3 below.

6.4.3 Assuring Quality of Data Content

Operating plans for programs that manually enter data into electronic systems address the needs and methods for the data to be validated and verified. To the extent feasible, systems will be designed to assist data entry operators in detecting and correcting invalid entries.

Operating plans for programs that maintain databases address the needs and methods to ensure that the contents conform to specifications and that data have not become corrupted over time. These methods may include periodic audits of database contents.

6.5 System Safeguards

Systems and data are protected against malicious and unintended loss and corruption through measures designed to restrict access, detect threats and reduce the probability of loss.

6.5.1 System Access

Access to systems is administered through the Maine DEP Computer Access Form. Users are set up to access only the systems they need to do their work. Access is controlled by user id/password authentication both at the desktop level and program application level. Access from equipment not physically connected to the State of Maine WAN is further authenticated by the use of SecurID technology.

6.5.2 Virus Protection

Computer viruses pose a significant threat to computer systems and the data stored on them. Maine DEP utilizes four levels of virus detection software:

- The Bureau of Information Services maintains first level detection at the firewall to the Internet

- Maine DEP maintains second level detection at the departmental MS Exchange e-mail server
- Maine DEP deploys third level detection at the desktop.
- Users are trained to check that their desktop anti-virus software is current and to practice “safe computing” procedures to prevent the infection and spread of computer viruses. These procedures are set forth in the ‘Maine DEP SOP for Preventing and Dealing with Computer Viruses’

6.5.3 Backup and Recovery

In order to safeguard against data loss, the Department backs up its server-based operating configurations, software and data on a regular basis and maintains multiple generations of media to support a roll-back to a prior version. Backups are scheduled, tested and media stored according to the “Maine DEP SOP for System Backups”. Users are directed to store all non-volatile data on servers that are covered by the backup plan or to create and maintain a system with equivalent safeguards. Only temporary copies of data are to be stored on hard drives not covered by a backup plan.

7.0 PLANNING

A systematic planning process is essential for ensuring that individual data operations will produce environmental data or information that are of the needed and expected quality for their intended use. Following such a process helps to ensure the ultimate success of any individual environmental data operation. Bureau directors are responsible for ensuring that a systematic planning process is used by directing planning teams to follow section 7.2 below. It is recognized that in addition to planned and long-term routine environmental data operations, there are also instances where the immediate need for a data operation arises from an unplanned event, emergency situation, or some other cause that imposes a constraint on the amount of time realistically available to meet the requirements of the formal systematic planning process and the development and approval of QAPPs as described below. Bureau directors shall use their discretion and best judgment in determining the flexibility needed from the requirements of this section in these instances, and document such in a memo to the file for that data operation.

In addition to planning specifically related to environmental data operations, Maine DEP and its several bureaus and program areas regularly engage in other planning processes, including, but not limited to

- ◆ Strategic planning to meet EPA , Maine State Government, and other requirements;
- ◆ Budget planning and financial management;
- ◆ Program planning on an annual or multi-year basis to meet external requirements to receive grants and other funding;
- ◆ Division, program and unit work planning.

Each unit of the Department, depending on its scope, is responsible for determining how such planning should take place, how frequently, and how the resulting plans are implemented and evaluated. All planning processes shall be documented, at a minimum, in a written plan.

The documented results of planning processes are also used to identify priorities for employee training and professional development; and to set individual performance expectations as part of the Performance Management Plan process (see 3.0). Managers and supervisors are responsible for assuring that employees are aware of their individual responsibilities and roles in implementing all applicable workplans.

7.1 Planning Teams

Before an environmental data operation begins, a planning team shall be organized by the responsible bureau. The team will consist of: 1) appropriate staff members who have knowledge and/or experience in the key areas of the data operation, such as sampling, analysis, quality assurance, quality control, and statistics; and 2) other appropriate stakeholders and interested or involved parties, such as members from EPA, outside

participating laboratories, municipalities, the regulated community, etc. It is the responsibility of the bureau director or his/her designee, to appoint a team leader, and to ensure that individuals with expertise in these key data operation areas are adequately represented on the team. For multi-media and/or cross-bureau operations, the Commissioner shall designate a lead Bureau to be responsible for organizing the planning team and ensuring staff representation from all appropriate bureaus.

7.2 Systematic Planning Process

The planning team at the outset will ensure that the following required elements (see EPA QA R/5) of the systematic planning process for an environmental data operation are addressed:

- a description of the goals, objectives, questions and issues to be addressed by the data operation;
- identification of schedules, milestones, and any applicable regulatory or contractual requirements;
- identification and allocation of resources (including a budget);
- identification and description of the type and quantity of data needed, and how the data will be used to support the operation's goals and objectives;
- specification of performance criteria for measuring quality;
- specification of quality assurance and quality control activities needed to assess the quality performance criteria (e.g. laboratory and field QC samples, performance audits, technical assessments, etc.);
- a description of where (sampling design), when and how (sampling and analysis procedures) the data will be obtained, as well as any constraints on data collection; and
- a description of how the data will be reviewed, evaluated and assessed against stated quality performance criteria and its intended use.

The above steps follow EPA's systematic planning process as described in the EPA document, "*Guidance for the Data Quality Objectives Process (EPA QA/G-4)*" (August 2000). The planning team will find it advantageous to refer to this document for additional background and information in addressing these required steps.

7.3 Quality Assurance Project Plans

The information, findings and descriptions resulting from the planning team's application of the systematic planning process for the environmental data operation shall serve as the basis for the development of a Quality Assurance Project Plan (QAPP) for that operation. Many of the required elements for an acceptable QAPP closely follow the steps described in the systematic planning process. The planning team shall to refer to the EPA documents "*EPA Requirements for Quality Assurance Project Plans (EPA QA/R-5)*"), and "*Region 1, EPA-New England Compendium of Quality Assurance Project Plan Requirements and Guidance*" for help in developing an acceptable QAPP.

Each bureau or program area is responsible for developing and implementing its own procedures for the development, review, approval, and periodic review or auditing of QAPPs for delegated and contracted activities written by entities outside Maine DEP's span of control. QAPPs for data operations overseen by BRWM's Division of Remediation may be written by the site owners, other responsible parties, and even EPA in lieu of a Bureau planning team. In such instances, the Division's approved SOP DR#016 (Attachment B in the "*Quality Assurance Plan for Maine DEP's Division of Site Remediation*" for QAPP development shall be followed.

7.3.1 Review and Approval of Quality Assurance Project Plans

Once the planning team has completed a QAPP for the environmental data operation under consideration, the QAPP shall be submitted for review and approval according to OC-QM-002, "QAPP Review," prior to the start of the data operation.

When signed approval has been received, official data operations may commence. The master copy of a QAPP shall be maintained in the program area responsible for the specified operations. All approved QAPPs shall be formally reviewed annually by the DEP employee responsible for maintenance of the document, and the results reported to the QAM. Minor revisions shall be documented and incorporated. Substantive revisions shall follow the requirements of OC-QM-002. For a summary of currently approved Quality Assurance Project Plans, see Appendix 3.

*Site-specific QAPPs developed for operations carried out to remediate RCRA state-led sites and Superfund sites need Project Manager approval only, as specified in approved QAPPs for these programs.

7.4 Other Quality Assurance Plans

Each bureau or program area develops procedures for the review and approval of Sampling and Analysis Plans (SAPs, also known as project plans or workplans) and other QA plans for the collection of environmental data for projects that do not require the development of a separate QAPP. All such plans will conform to the EPA Graded Approach in determining the appropriate level of detail. Where such plans involve the use of new or experimental methodologies, the relevant procedures shall include a provision for external or other peer review prior to use, and a post-event effectiveness review.

7.5 Evaluating Data Collected Outside of this Planning Process

For data collected by an operation outside of the planning processes described here, or by an organization outside of Maine DEP that attests a systematic planning process was used, an existing or previous Maine DEP planning team for the environmental data operation having the closest similarities to the outside data in question may be

asked to evaluate them for usability. This may be done by comparing as many documented aspects of the outside data operation as possible to the elements of its approved-QAPP counterpart. The team will need to evaluate how closely they agree, and where differences exist determine if they are substantial enough to allow the use of the data with qualifications (e.g. greater or lesser statistical confidence levels), or not allow the use of the data at all. The evaluating team will document their findings in a written report along with their recommendations on the usability of the data.

Each program area shall be responsible for developing and documenting standards of acceptance, and procedures for reviewing, verifying, and validating environmental data procured or provided by entities outside Maine DEP's span of control (2nd party data) not otherwise subject to a QAPP. SOPs, DQOs, DQIs, SAPs and related documentation of such standards and procedures shall be maintained in a central location in each DEP division.

8.0 IMPLEMENTATION OF WORK PROCESSES

Maine DEP uses SOPs to ensure that certain kinds of regularly performed activities, such as sampling techniques, operational procedures, or boilerplate document drafting, are conducted uniformly and appropriately given the needs of a task. Written SOPs help to ensure standardization of work on a site or for a program. SOPs are required with a QAPP for certain types of site work to allow the Maine DEP to verify acceptable procedures are being used. SOPs submitted with the QAPP must be used in implementing the project and will be used when auditing work. All program areas are responsible for developing, documenting, and implementing standard procedures for appropriate routine, standardized, special or critical operations, particularly those involving collecting, compiling, storing or analyzing environmental data.

8.1 Activity Standardization

In conjunction with the auditing program described in Element 9 of this QMP, Maine DEP uses its *Standard Operating Procedure Development, Format, Approval, and Distribution* (OC-PE-0001, Revision 01, Effective 5/15/01) document to guide staff and management in standardizing regularly performed activities. This document is included in this QMP as Appendix 4. This procedure defines the process for procedure standardization, SOP preparation, content, format, review, approval, release, revision, archival, and procedure withdrawal.

8.2 SOP Implementation

Maine DEP uses the auditing program described in Element Nine and the management oversight and performance appraisal programs described in Element One of this QMP to ensure that approved QAPPs and SOPs are implemented. These channels of authority and implementation mechanisms address scheduled and unanticipated changes to SOPs.

9.0 ASSESSMENT AND RESPONSE

Maine DEP has developed a program to monitor conformance to and assess the effectiveness of the Quality Management System. Assessments will take a number of forms within the Department, including:

- data quality assessments;
- employee performance evaluations,;
- program reviews;
- peer reviews;
- formal audits;
- management system reviews; and
- EPA assessments.

Assessments, including formal audits, are based on quality objectives as documented in this QMP, Quality Assurance Project Plans (QAPPs), standard operating procedures, technical or professional standards, or other requirements set prior to work being performed. The type and frequency of assessments are determined in the systematic planning process (7.2), and recorded as part of a QAPP, SAP, or similar document. Assessment results are reported to appropriate management, supervisory, and other personnel for review and action as necessary. The assessors or auditors are qualified individuals from the Department who are independent of the area being assessed, or from a contracted source.

Where program or project areas have yet to develop documented standards against which to assess conformance, management may request that the QMSC develop and carry out an evaluation audit. The audit team will work with program staff to determine the scope of the proposed audit, and will then compile an audit checklist based on the relevant ANSI/ASQ E-4 and QMP standards. The audit will follow the standard “condition expected / condition found” protocol for quality auditing. Program, division, and bureau management will receive an audit report, and Corrective Action Requests, outlining actions needed to reach the standard (see Appendix 5). In addition, the audit report will include findings and recommendations intended to provide guidance for process improvements.

During development of annual budgets and work plans, lead quality assurance staff in each bureau prepare written assessment plans for their programs. Lead quality assurance staff consult with grant, program, project managers, and other staff as necessary in developing these plans.

Annual assessment plans list the programmatic and project-related assessments planned for the current fiscal year as well as the scope, lead assessor, and anticipated date of each assessment. Annual assessment plans and any revisions to those plans are approved by the QMSC prior to implementation.

The Department procedure for quality auditing is included in Appendix 5.

9.1 Data Quality Assessments

Laboratory data received by the Maine DEP are assessed based upon the intended use of the data. Each program or bureau establishes the acceptance criteria needed for data assessment. Other types of submitted data, such as field data or reports, are assessed for quality by qualified technical staff in each program using the QAPP or data quality assurance procedure established by that program. Program managers are responsible for assuring that data received are checked for completeness, and assessed for usability in meeting project objectives.

Data submitted by the regulated community pursuant to a license condition are reviewed and verified by DEP technical staff as part of regular inspections. Each program receiving such data establishes and documents its own assessment standards and procedures.

9.2 Employee Performance Evaluations

Employee performance evaluations are performed following guidance provided by the Bureau of Human Resources, and are documented on Performance Management Forms. See Section 3.3. Individual performance plans specify appropriate general or specific responsibilities for carrying out the provisions of this QMP. Managers and supervisors are evaluated for their implementation of QMS responsibilities.

9.3 Program Reviews

A program review team to assess whether program objectives, policies, methods, documents and procedures are up-to-date and consistent with Legislative and Department goals and priorities conducts program reviews. Bureau Directors will determine the need for and timing of program reviews. The QMSC may recommend to senior management that a program be reviewed, based on results of a management review (See Section 10.2).

9.4 Peer Reviews

A peer review process may be used when the Commissioner or a Bureau Director determines that an action by the Department or sponsored by the Department requires an independent technical review of data or analyses in order to ensure accuracy, credibility and applicability. The Department (or each bureau) will maintain guidelines for conducting a peer review.

9.5 Formal Audits

The Department carries out a program of formal audits to assess conformance to each element of this Quality Management System and to individual QAPPs, SOPs, Department rules, or other Department policies or requirements. A program manager according to quality objectives and risk may schedule audits of outside laboratories, contractors or suppliers. Audits are conducted according to the procedure established by the Department (Appendix 5), plus any additional requirements that may be established

by each bureau, office or program. Additional requirements are documented as part of a specific audit plan.

Qualified individuals who are independent of the area being audited conduct audits. They are conducted in a rigorous systematic manner, using objective evidence to make findings regarding non-conformance to requirements and the need for any corrective action. Audit findings are documented and reported in a timely fashion to management. Proposed corrective actions are evaluated and tracked, and the effective implementation of corrective actions is verified before the audit is closed.

The Department may rely on or require third party audits, such as laboratory certification or ISO 9001 certification, in lieu of conducting its own audits.

9.6 Management System Reviews

The Quality Management System will be assessed on an annual basis by an internal management system review team, as described in Element 10.

9.7 EPA Assessments

EPA sponsored programs are subject to review or audit by EPA. Scope and timing of audits may vary depending on the program and its enabling legislation, rules or authorities. Formal assessment of performance under EPA Performance Partnership Agreement occurs as part of a comprehensive review and evaluation of Department programs. The process is governed by EPA's Policy on Oversight of Delegated Programs, which states evaluations should focus on overall program performance.

9.8 Deficiencies and Nonconformances

Significant deficiencies and non-conformances to QAPPs, SOPs or Department requirements observed outside of a formal audit or assessment process are reported by Department staff to supervisors.

Each Division Director or program manager shall establish who has authority to suspend or stop work upon detection and identification of an immediate adverse condition affecting quality or health and safety.

Supervisors shall ensure that the deficiency or non-conformance is documented, and shall forward reports to the appropriate project manager and lead quality assurance staff. A formal Corrective Action plan may be required, and tracked until closure.

9.9 Corrective Actions

Corrective actions generally are developed on a case-by-case basis. Once a problem has been identified, the problem is documented and individuals involved with the project are notified of the problem. Involved parties (including project managers) meet to discuss the problem.

When deficiencies or non-conformances have been identified, project managers determine and document the following:

- the nature and scope of the problem
- the root cause(s);
- the programmatic impact;
- required corrective action(s)
- action(s) needed to prevent recurrence, including training;
- method of assessing and verifying the effectiveness of the corrective action;
- timetable for implementation; and
- the staff responsible for implementation and follow up reporting.

The project manager forwards copies of corrective action plans to supervisory and lead quality assurance staff involved in monitoring corrective actions. Lead quality assurance staff forward copies of corrective action plans, as appropriate, to affected division directors, grant and program managers.

Managers and supervisors ensure that corrective action plans are effectively implemented in a timely manner, and that activities necessary to carry out such plans are included in annual workplans or other planning documents as appropriate. Bureau directors and lead quality assurance staff monitor the implementation of corrective action plans. Managers and supervisors shall include completion of corrective actions in employees' performance management plans and annual performance review.

Non-conformances and corrective actions are documented in the project or program file to ensure that future individuals involved with the project or activity will be able to trace the evolution of procedural or policy change (including what was done, by whom, and why).

10.0 QUALITY IMPROVEMENT

Maine DEP understands “quality improvement” to be a continuing process by which the Department identifies opportunities to improve the Quality Management System itself, as well as individual programs and work processes. It thus continues, but is distinct from, efforts to assure Quality Control and Quality Assurance.

All Maine DEP employees and contractors are encouraged to identify, plan, implement and evaluate quality improvement activities for their areas of responsibility. Individual employees prevent quality problems whenever possible, and report opportunities for improvement as well as quality system problems as they are identified.

The method for addressing deficiencies and non-conformances is described in Element 9.8.

10.1 Quality Management System

Maine DEP’s Senior Management Team requires the QMSC (see 2.1) to report annually on the state of the QMS. This report, based on an internal review or formal audit (see 9.6), identifies areas of the QMS in need of correction or improvement, makes recommendations for implementing needed change, and specifies the resources needed for implementation. Senior Management then determines how the recommendations should be carried out, and allocates the necessary resources.

On an annual basis, bureau quality management coordinators review quality-related deficiencies, non-conformances, and programmatic improvements and advise the affected program manager, bureau director, and quality assurance manager of any significant trends.

On an annual basis, the Quality Assurance Manager provides the EPA-New England Quality Assurance Officer with a report describing the status of the Quality Management System.

10.2 Organizational Improvement

Opportunities for improvement of Maine DEP processes and programs beyond the requirements of this QMP are identified in a number of ways, among which are:

- Ongoing processes associated with State Performance Budgeting; annual and multi-year Strategic Planning; and the Performance Partnership Agreement with EPA;
- The auditing and assessment processes described in Element 9.0; and
- Ongoing management review at the program and Division level (see 9.3)

Where opportunities for improvement are identified, management determines how these might be implemented, and allocates the necessary resources.

10.3 Customers and Stakeholders

In addition to opportunities identified within Maine DEP, the Department uses a number of different methods to receive and act on suggestions for improvement from customers and stakeholders. These include, but are not limited to,

- Solicited comments from the regulated community and general public through workshops, focus groups, and other formal stakeholder processes;
- Unsolicited comments from the regulated community, general public, and other interested parties;
- Consultation with legislators and other state agencies; and
- The rule-making process overseen by the Board of Environmental Protection.

Management is responsible for receiving such comments and suggestions, and determining how best to act on them to fulfill the Department's mission.

10.4 Quality Recognition

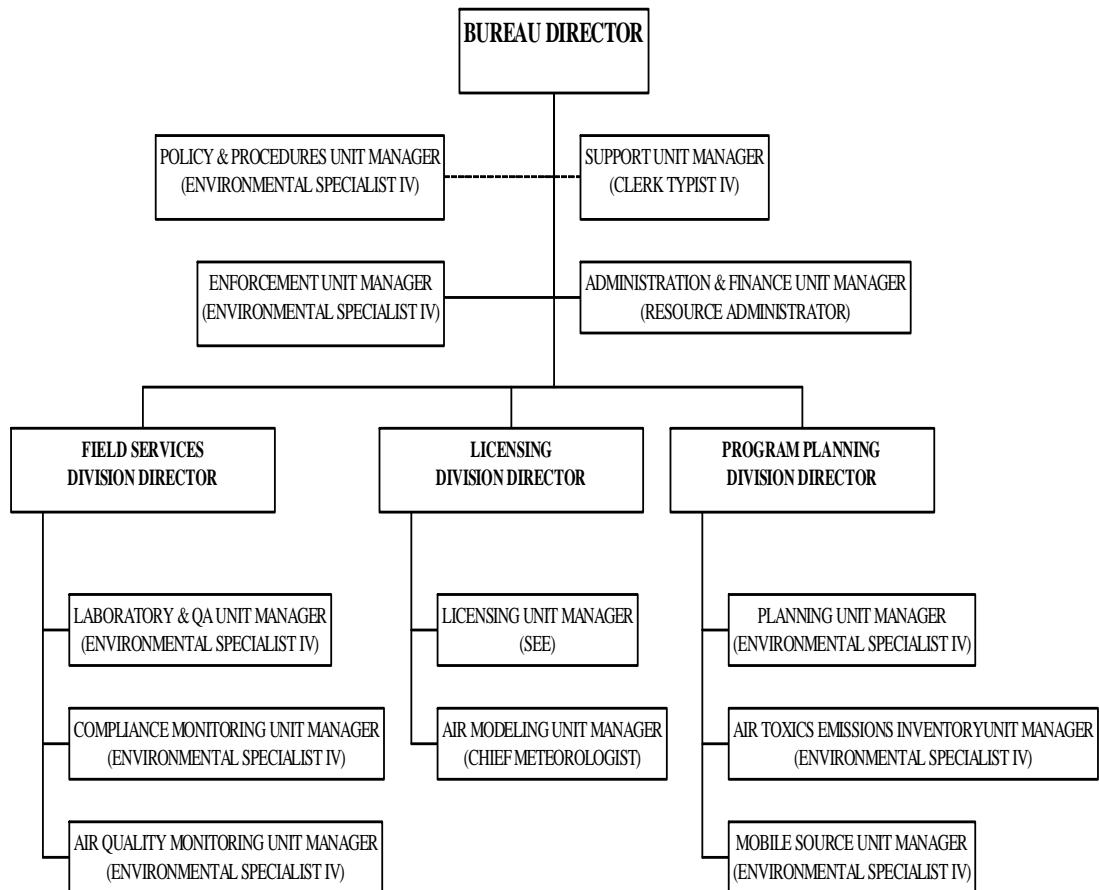
Maine DEP has instituted an annual Quality Improvement Award, given each year at the Employee Recognition Day event, to recognize outstanding contributions by individuals or teams to the ongoing quality effort of the Department. In addition, the "Employee of the Month" program, as well as both Department and state-level awards to individuals and teams, includes quality as a component in the selection criteria.

APPENDIX 1

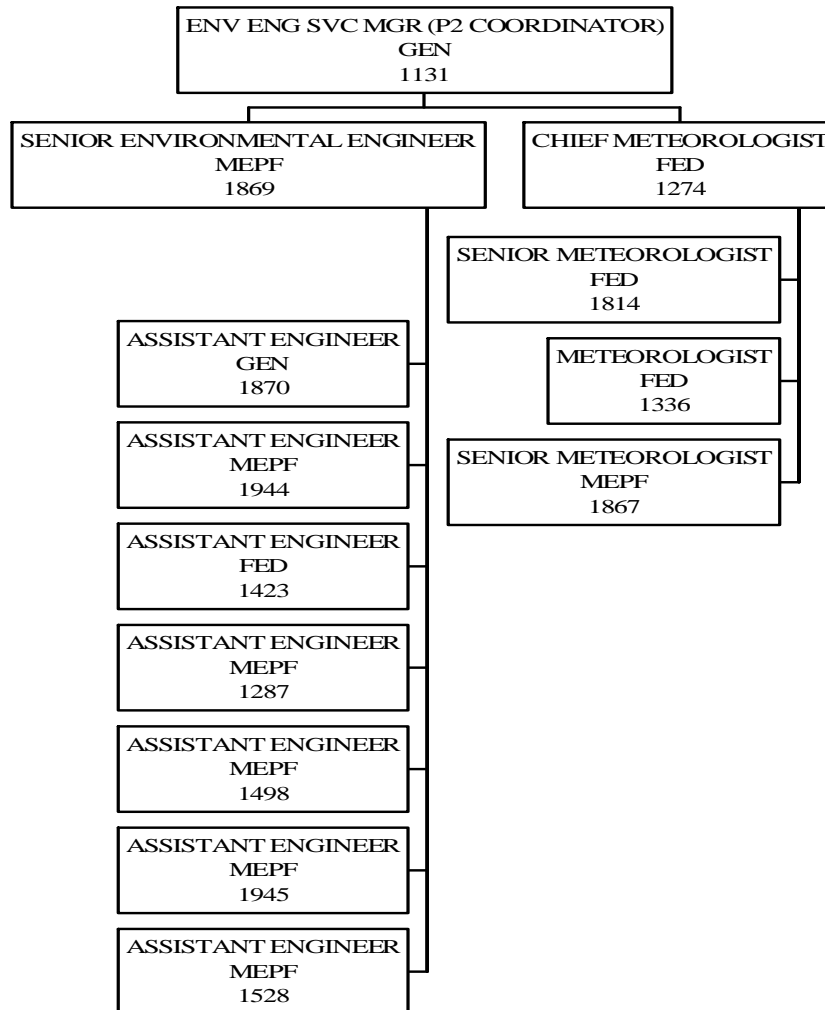
ORGANIZATIONAL CHARTS

Bureau of Air Quality

Management Overview



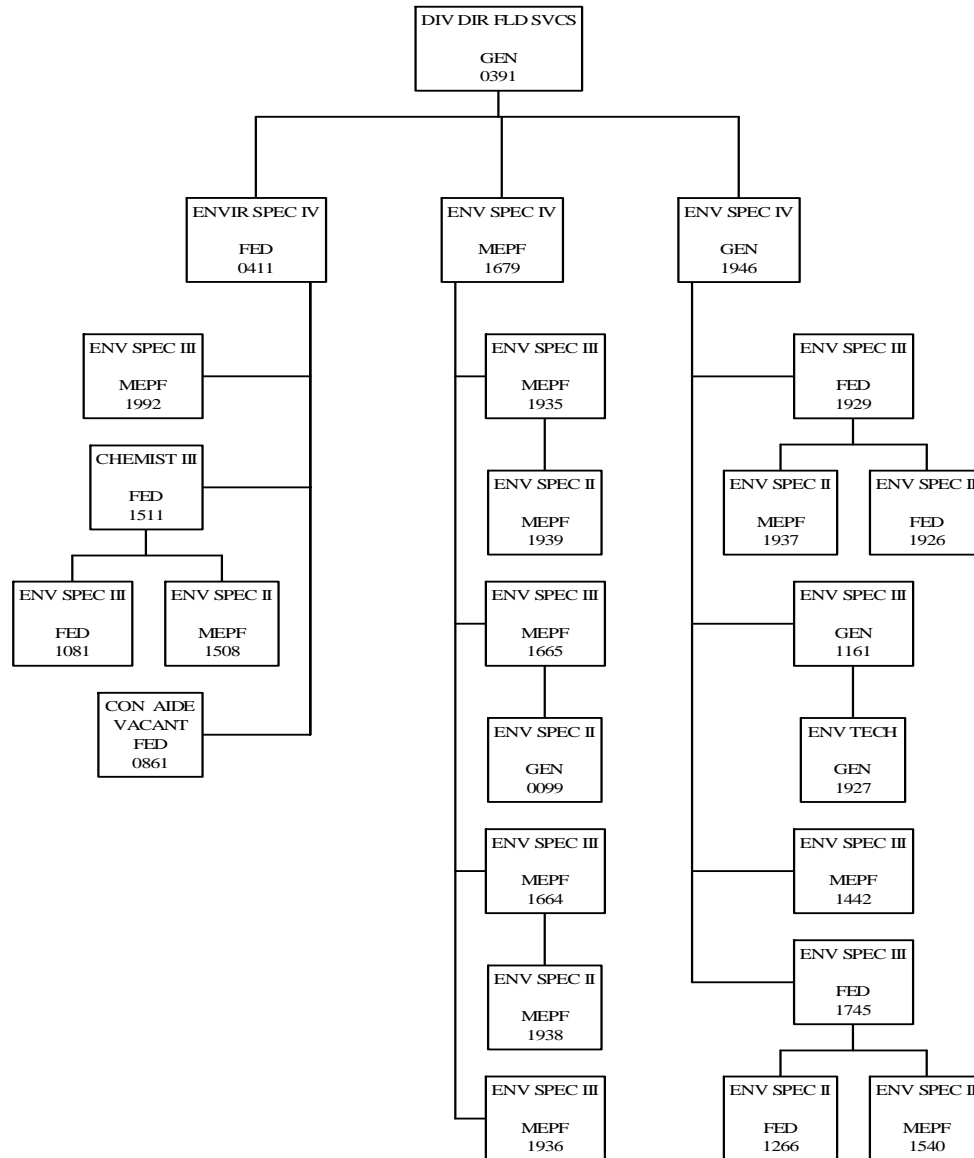
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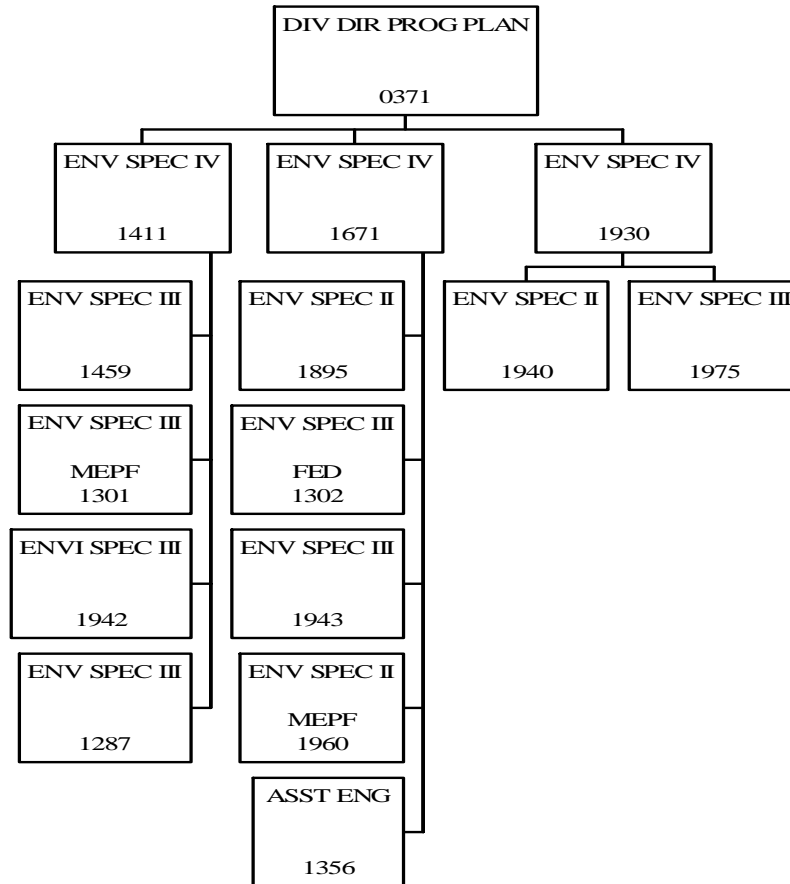
LICENSING

Bureau of Air Quality



FIELD SERVICES DIVISION

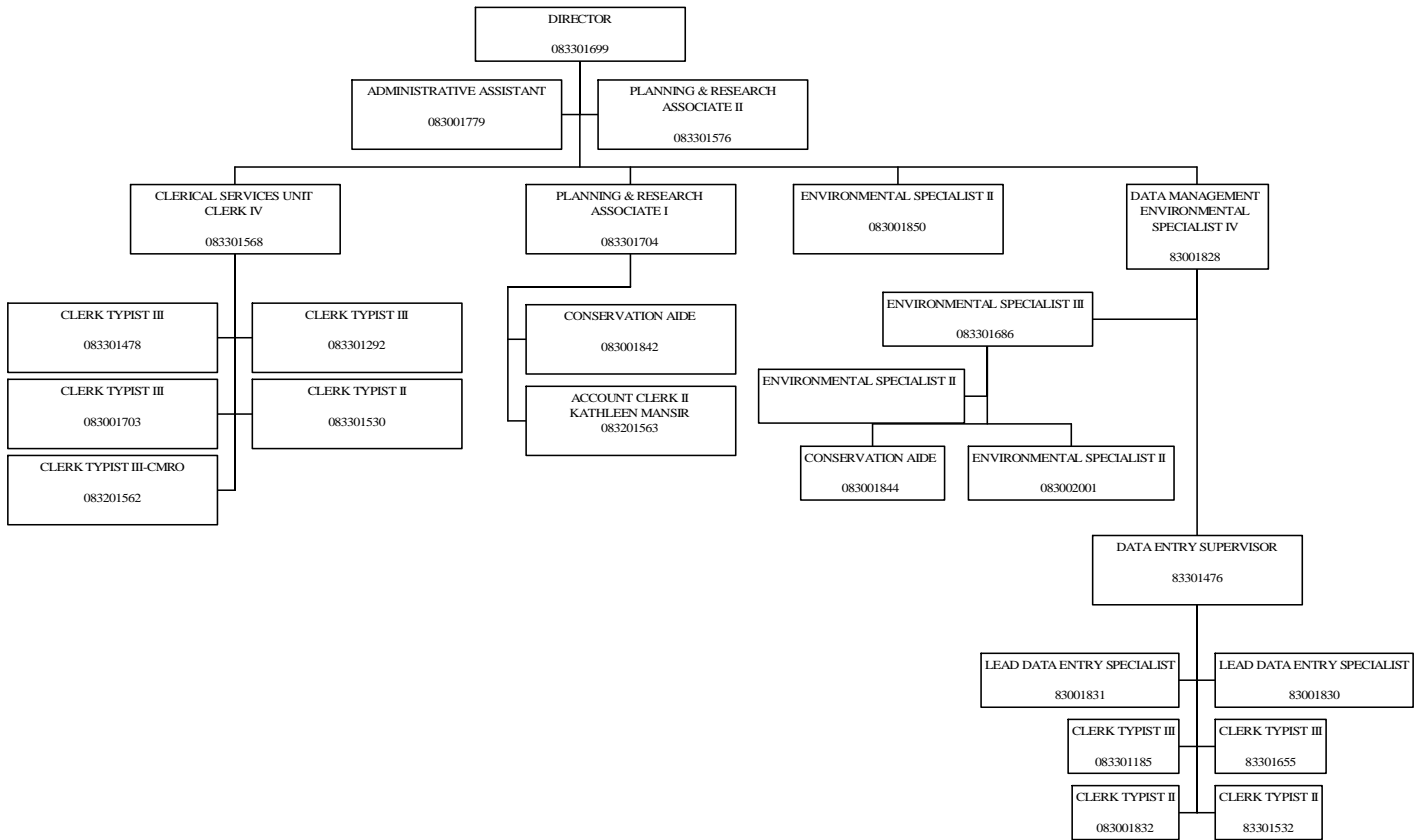
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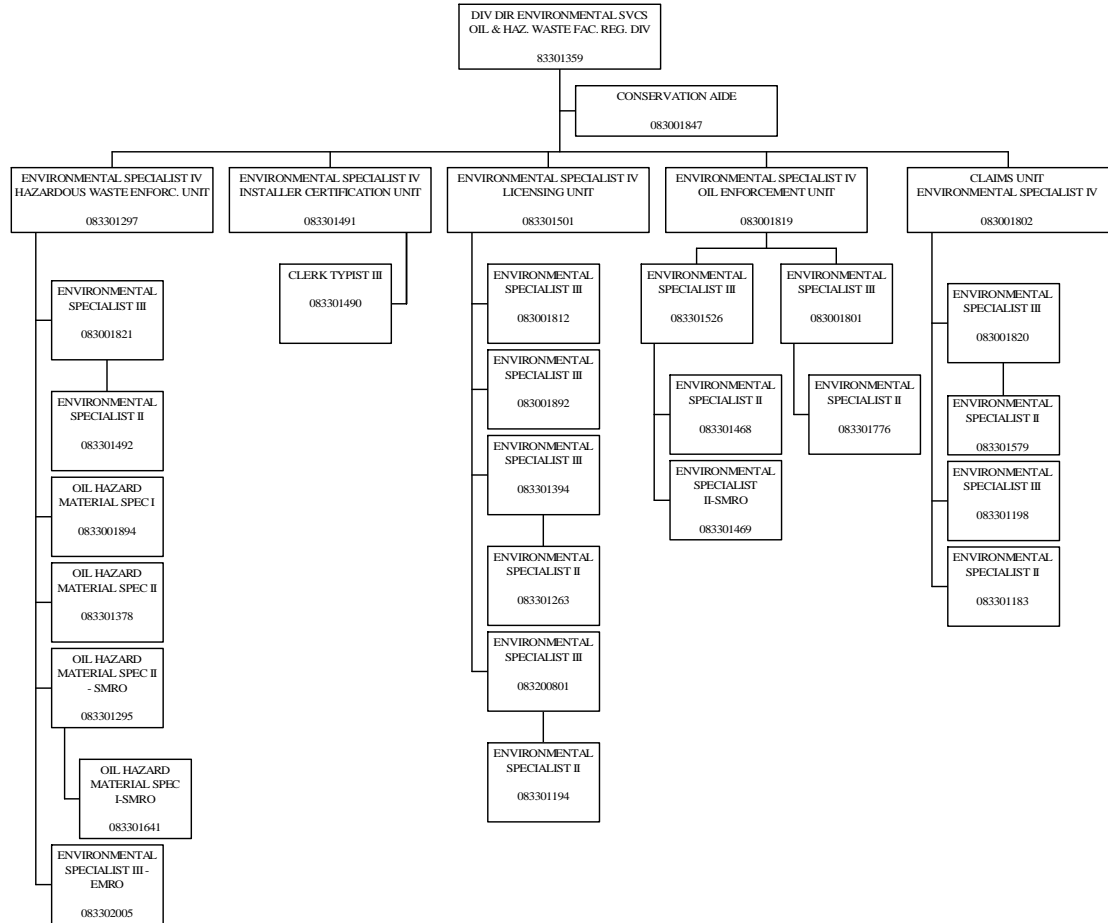
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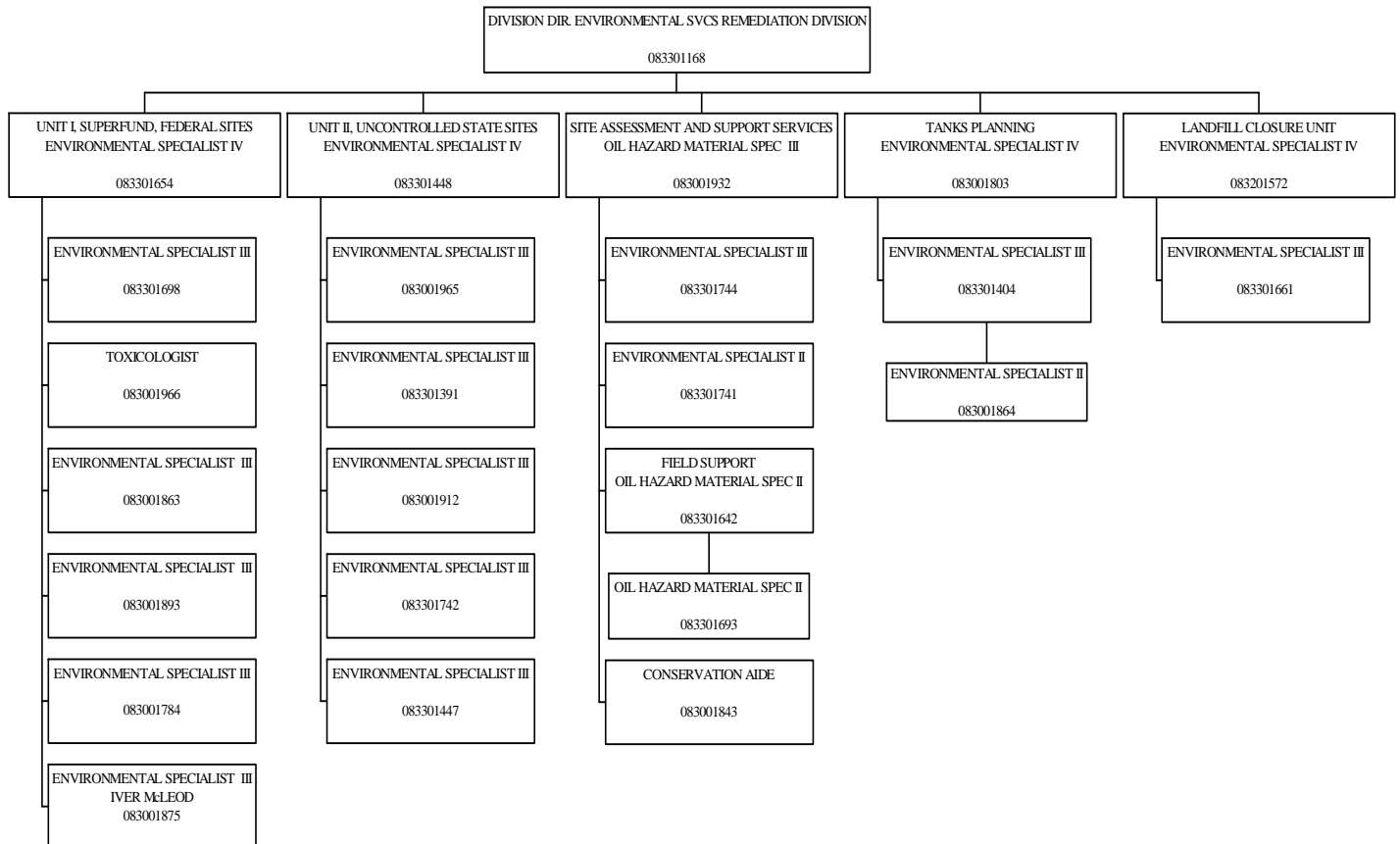
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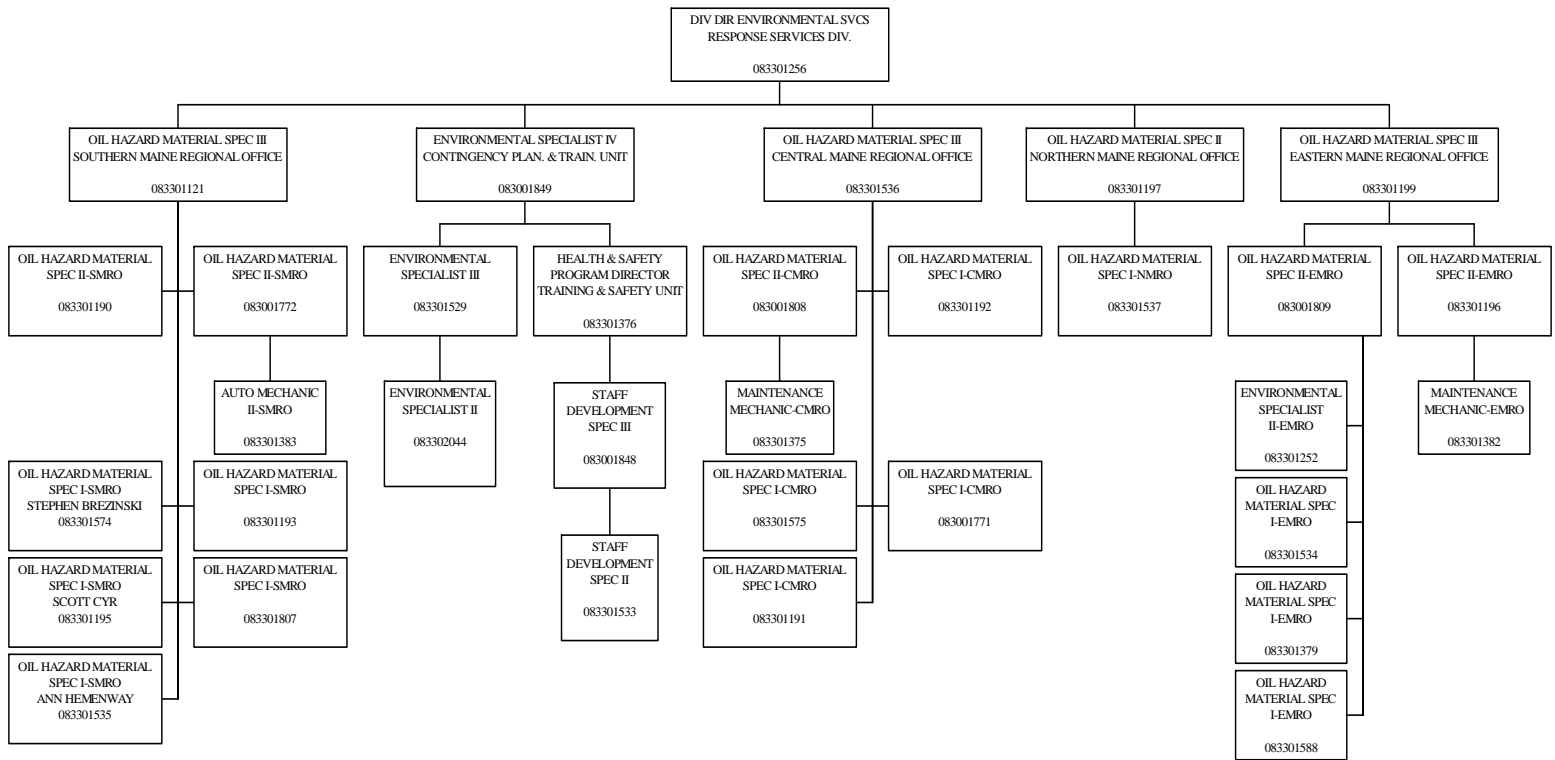
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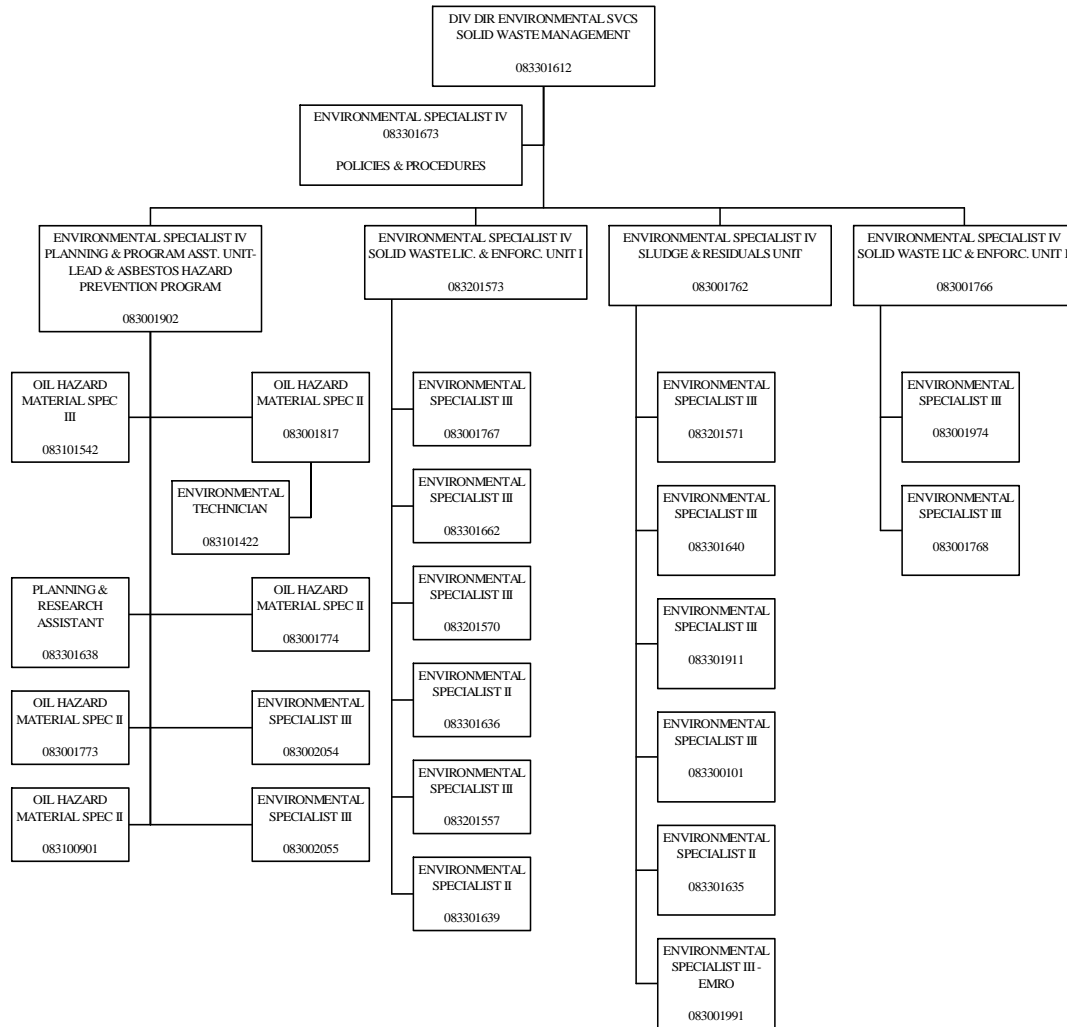
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Bureau of Remediation & Waste Management

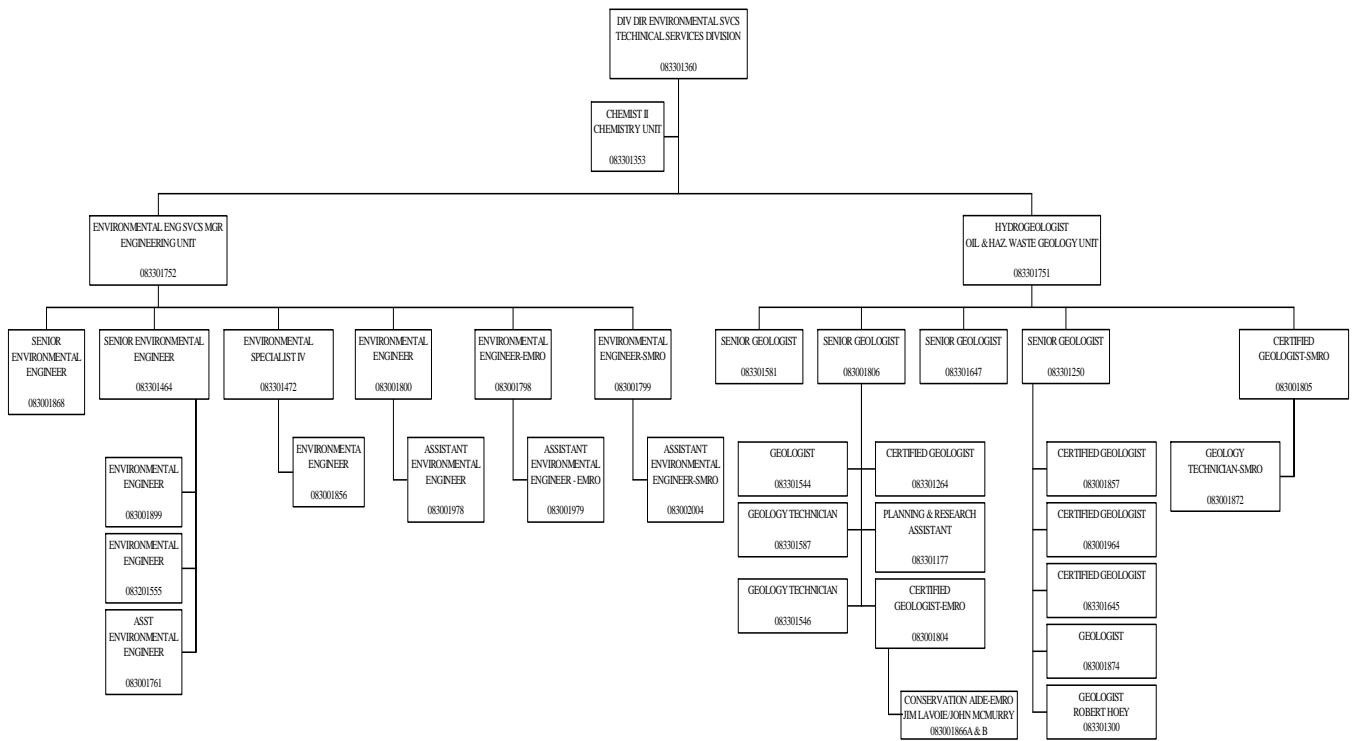


Bureau of Remediation & Waste Management

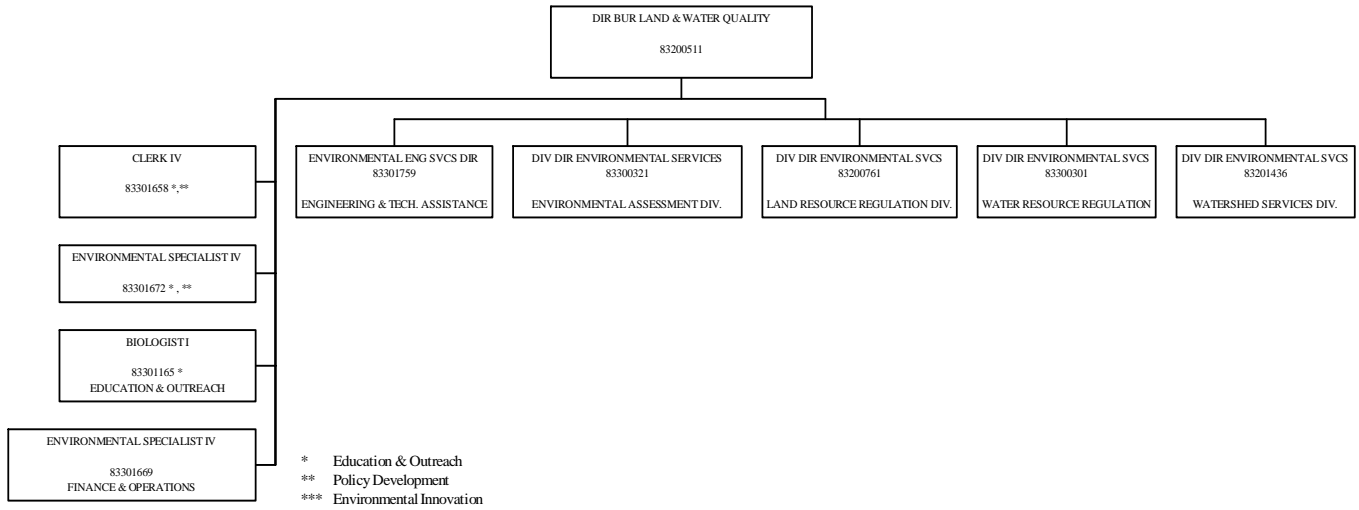


SOLID WASTE MANAGEMENT DIVISION

Bureau of Remediation & Waste Management



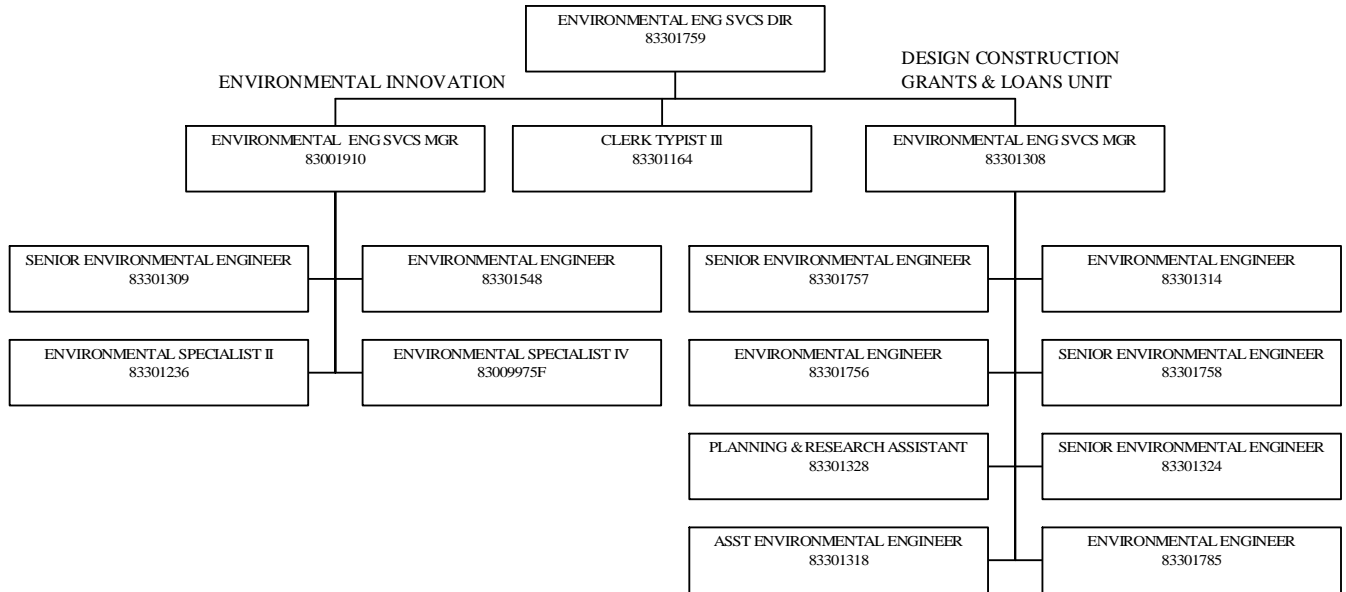
Bureau of Land & Water Quality



OVERVIEW

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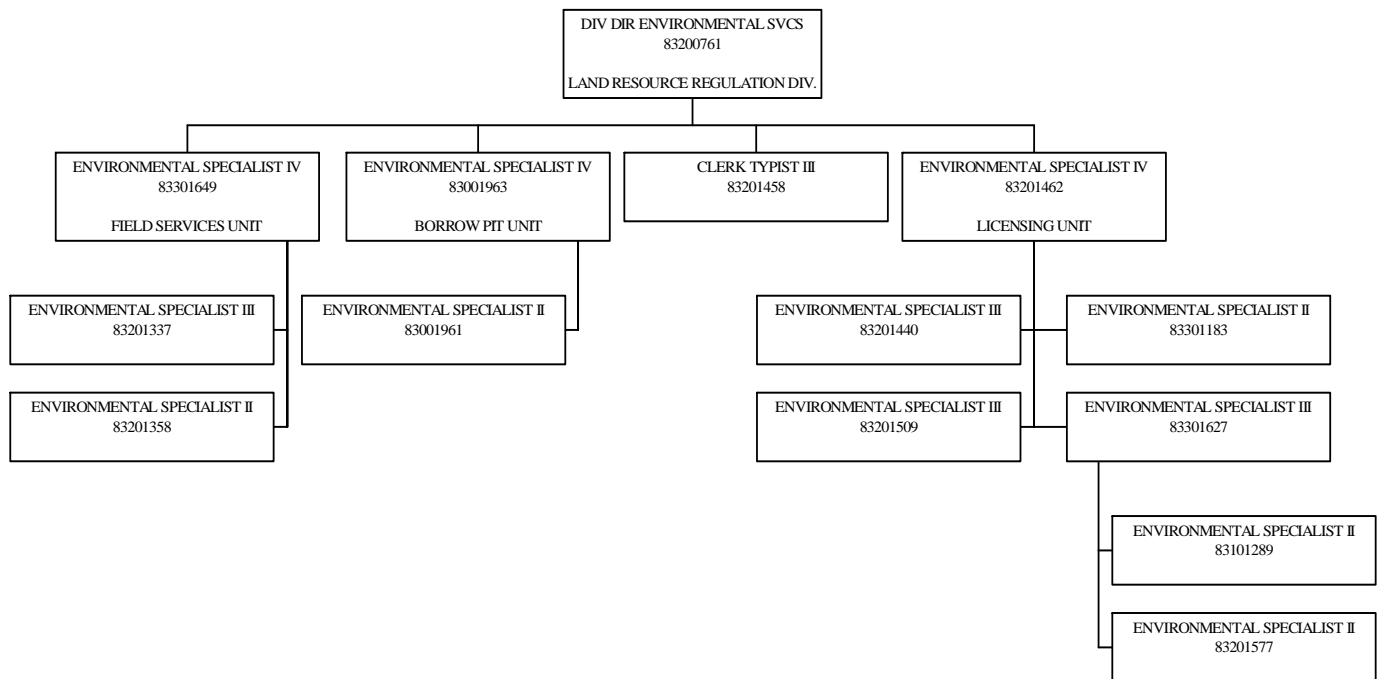
Bureau of Land & Water Quality



ENGINEERING & TECH. ASSISTANCE DIVISION

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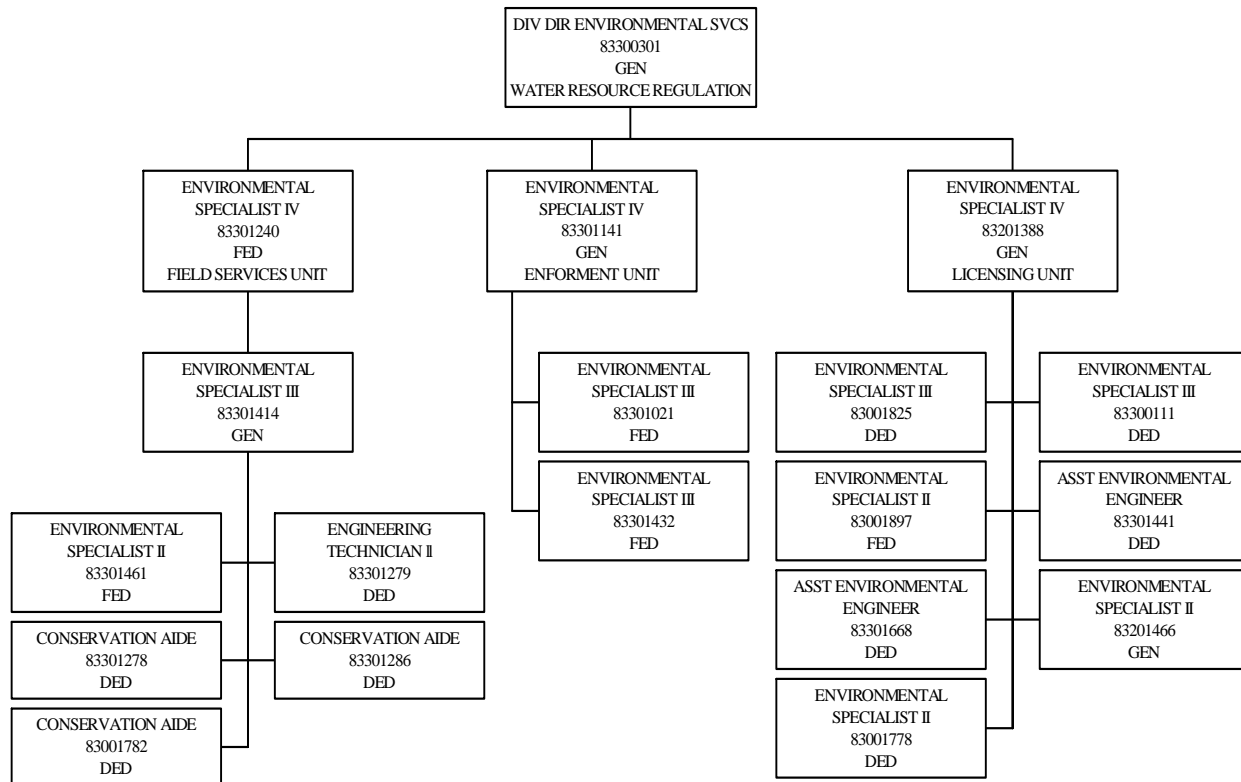
Bureau of Land & Water Quality



LAND RESOURCE REGULATION DIVISION

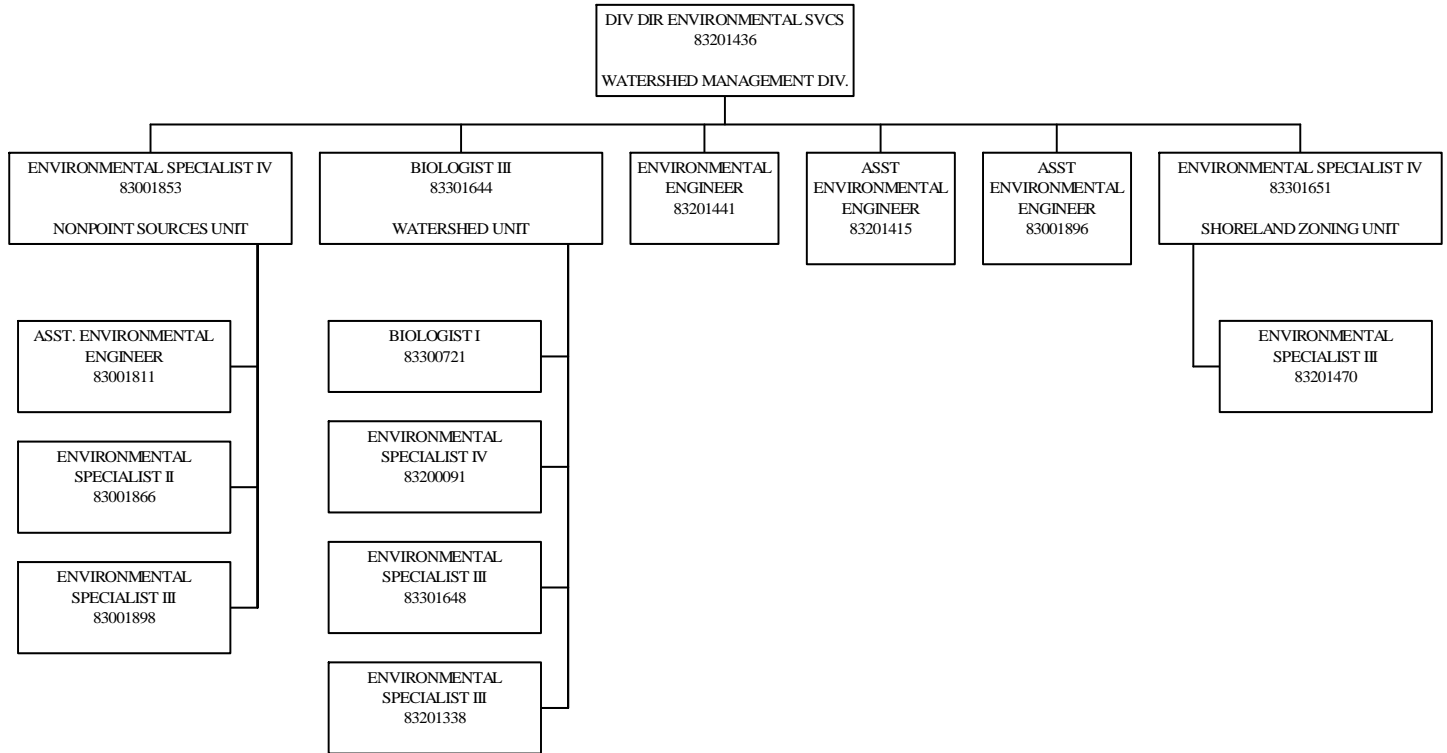
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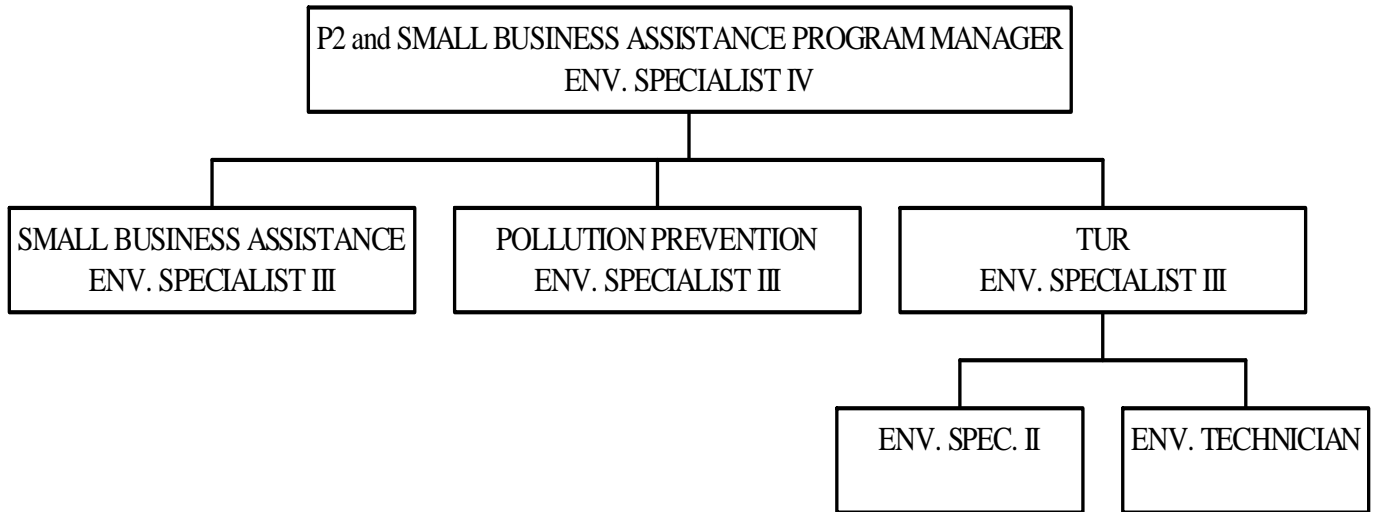
WATER RESOURCE REGULATION DIVISION

Bureau of Land & Water Quality



WATERSHED MANAGEMENT DIVISION

OFFICE OF INNOVATION AND ASSISTANCE



APPENDIX 2:

QUALITY MANAGEMENT POLICY FOR ENVIRONMENTAL DATA

Intent: It is the policy of the Maine Department of Environmental Protection (MEDEP) to ensure that its operations are consistent with defined standards, criteria, and procedures in order to maintain the highest appropriate levels of quality. To this end, the Department operates in accordance with a Quality Management Plan (QMP, May, 2001, as revised)) that defines such standards, and provides the basis for quality improvement. The Quality Management System described in the Plan applies to all areas of DEP operations, and includes consideration of the needs and expectations of the Department's customers and stakeholders.

Quality Control (QC), Quality Assurance (QA), and Quality Improvement activities related to the collection, analysis, storage and use of environmental data are prescribed in the Department's Quality Management Plan (QMP. These activities, responsive to the criteria in the ANSI/ASQC – E4 and ISO 14001 (1996) standards, are necessary to ensure that decisions made by the Department are based on data management methods and practices that meet or exceed relevant quality standards.

Standards: It is the policy of the MDEP to ensure that:

- ◆ Management provides the resources necessary to develop, implement, maintain, and improve the QMS; and regularly reviews the performance of the QMS for effectiveness in supporting the stated mission of the DEP;
- ◆ Standard Operating Procedures (SOPs) are established for key processes as determined by each Bureau, Division or Office;
- ◆ Environmental data meet documented standards for accuracy, precision, representativeness, comparability, and suitability to their intended purposes;
- ◆ Environmental data are verifiable and defensible, and all components related to their generation are properly documented;
- ◆ Environmental technologies, including those for sampling and monitoring, are designed, constructed, and operated according to defined expectations;
- ◆ Data integrity is maintained and documented, including chain-of-custody and archival control;
- ◆ Quality audits of QMS elements are carried out on a scheduled and documented basis, as is resulting necessary corrective action;
- ◆ Managers, supervisors, and staff throughout MEDEP, and its contractors, understand their roles in managing quality; receive the training necessary to meet quality standards for job tasks; and are encouraged to identify and suggest improvements to be made to the QMS.

Responsibility:

1. The Senior Management Team (SMT) of MEDEP shall appoint a Quality Management Steering Committee (QMSC), convened by the MEDEP Quality Assurance officer, charged with oversight of all QMS activities.

2. SMT is responsible for ensuring that QMS programs and requirements are implemented in the several Bureaus and other organizational units of MEDEP. This responsibility includes, but is not limited to, ensuring that personnel and other resources are available to meet the standards above, and the requirements of the QMP.

Martha G. Kirkpatrick, Commissioner

May 15, 2002

APPENDIX 3:

SUMMARY OF EXISTING QAPPS AND RELATED DOCUMENTS

SUMMARY OF EXISTING QAPPS AND RELATED DOCUMENTS

<u>Bureau</u>	<u>Program Area</u>	<u>Type of QAPP</u> (generic or project specific)	<u>Completion Status</u>	<u>Comments</u>
Air	PM 2.5	Generic	Approved, 7/99	
Air	Ambient Measurement Systems	Generic	Approved, 6/87	To be reviewed, 2001
Air	PM 10	Generic	Approved, 1/91	To be reviewed, 2001
Air	PAMS	Generic	Approved, 9/95	Revised and re-approved, 2000
Air	Portland UV DOAS EMPACT	Project specific	Approved, 5/99	
Air	Emissions inventory database	Generic	In development	? 12/2001

Remediation	Leaking Underground Storage Tanks	Program specific	Submitted, 1/96	Awaiting approval
Remediation	RCRA Program	Program specific	Submitted 2/95	Awaiting approval
Remediation	Division of Site Remediation	Program specific	Approved 6/7/99	

LW	Fish Tissue Contamination in Maine	Generic	12/20/93; approved	Project no longer active, but protocols remain in force
LW	Gulfwatch Project Field Sampling SOP	Project specific	1994; approved	
LW	Groundwater Resource Database Quality Assurance Plan		1/97	Not a QAPP; being revised, 2001
LW	NPS Impacted Streams Biological Assessment	Project specific	2/97, approved	
LW	Casco Monitoring: Dissolved Oxygen	Project specific	10/97, approved	
LW	Casco Monitoring: Sediment Toxicity Bioassay	Project specific	2/97, approved	
LW	Lakes Volunteer Monitoring	Generic	9/96, approved	Renewal application in progress
LW	Salmon Falls / Piscataqua Rivershed TMDL	Project specific	4/95, revised	Project completed
LW	StormTreat system	Project specific	1999;	

	evaluation		approved	
LW	Leachate control: manure field stacking	Project specific	1999; approved	
LW	Cobbossee Lake restoration	Project specific	2000; approved	
LW	Sheepscott River: WQ restoration	Project specific	2000; approved	
LW	Frost Gully watershed retrofit	Project specific	1999; approved 2000	
LW	Meduxnekeag River restoration	Project specific	2000; approval pending	
LW	Tannery Brook WQA	Project specific	1999; approved	
LW	Goose Fare Brook WQA	Project specific	9/99; approved	
LW	Long Creek Comprehensive WQ Evaluation	Project specific	early 2000; approved	
LW	Kents Hill School Erosion and Sedimentation Demo Project	Project specific	Submitted 9/99; approval pending	
LW	Headwater Streams: Road Runoff	Generic	9/99, approved	
LW	Casco Bay Sediment Contamination Assessment	Project specific	7/2000; approved	
LW	Characterizing Flow of Effluent / Movement of Nutrients from Stockpiled Biosolids	Project specific	In development	
LW	New Meadows River / Spruce Creek Sediment PAH Analysis	Project specific	Submitted 10/2000	
LW	319 NPS Small Grants	Generic	early 2002	

APPENDIX 4:

**STANDARD OPERATING PROCEDURE DEVELOPMENT, FORMAT,
APPROVAL AND DISTRIBUTION**

IDENTIFICATION NO.: OC-PE-0001

**COVERSHEET
STANDARD OPERATING PROCEDURE**

Operation Title: **Standard Operating Procedure Development, Format, Approval and Distribution**
Identification No.: **OC-PE-0001**
Revision No.: **01**
Originator Name: **Jim Dusch**
Effective Date: **May 15, 2001**

APPROVALS:

Bureau Director:

Print Name Signature Date: _____

QMSC Chair:

Print Name Signature Date: _____

Deputy Commissioner on behalf of SMT:

Print Name Signature Date: _____

Other:

Print Name Signature Date: _____

DISTRIBUTION:

() Bureau of Air Quality By: _____ Date: _____
() Bureau of Land and Water Quality By: _____ Date: _____
() Bureau of Remediation and Waste Management By: _____ Date: _____
() Office of the Commissioner By: _____ Date: _____
() Quality Management Steering Committee By: _____ Date: _____

1. **PURPOSE.** Establishing standardized methods for performing common repetitive tasks improves the Maine Department of Environmental Protection's (Department) efficiency, consistency, verifiability, credibility, and our ability to attain the highest levels of Quality Assurance, Quality Control, and Quality Improvement. This document describes the Department's procedure for developing, formatting, approving, and distributing standard operating procedures (SOPs). This procedure applies to all staff involved in any task that is appropriate for, or has an established, SOP.

This SOP repeals and replaces OQA-0002 (Revision 01), which contained provisions now addressed in this document.

2. DEFINITIONS.

- 2.1 COMMISSIONER. The term *Commissioner* refers to the Commissioner of the Department of Environmental Protection.
- 2.2 DEPARTMENT OF ENVIRONMENTAL PROTECTION. The term *Department of Environmental Protection* or *Department* refers to the Maine Department of Environmental Protection, a State administrative agency.
- 2.3 QUALITY MANAGEMENT STEERING COMMITTEE. The Maine DEP organizes and oversees agency-wide QA/QC/QI functions with a *Quality Management Steering Committee* (QMSC). Six (6) management level individuals comprise the QMSC, with at least one (1) representative being from each bureau and one (1) member being from senior management.
- 2.4 SENIOR MANAGEMENT TEAM. The term *Senior Management Team* (SMT) refers to the group of individuals existing at any point in time that have been chosen by the Commissioner to oversee Department management.
- 2.5 STANDARD OPERATING PROCEDURE. The term *Standard Operating Procedure* (SOP) is the description of a prescribed method that must be used by Department staff to complete certain routine or repetitive operations, analyses or action. These procedures are commonly accepted as the preferred method. Standard Operating Procedures do not establish policy.

3. RESPONSIBILITIES

- 3.1 All staff engaged in operations, analysis or actions subject to or appropriate for the application of a SOP are responsible for becoming familiar with and complying with the contents of this procedure prior to drafting a SOP.
- 3.2 Supervisors are responsible for ensuring that their groups are familiar with and adhere to the SOPs affecting their program's functions.
- 3.3 The staff of the originating unit will be responsible for initial development. Initial development includes word processing and distribution for review.

- 3.4 Office of the Commissioner clerical staff will be responsible for the following:
 - 3.4.1 Maintaining electronically and in paper form a *Standard Operating Procedures Master File* that includes computer files saved in the version of Microsoft Word and Adobe Acrobat currently licensed to the Department.
 - 3.4.2 Generating and maintaining electronically and in paper form an index of the Master File referred to in 3.4.1 of this SOP in Index.
 - 3.4.3 Assigning identification numbers to all SOPs based on the Identification and Coding System appended to this SOP as Figure 4.
 - 3.4.4 Distributing approved SOPs.
- 3.5 The QMSC maintains the SOP master file.

4. GUIDELINES AND PROCEDURES

- 4.1 ORIGINATION. A staff member may originate a draft or concept for a draft SOP for any appropriate procedure or process.
- 4.2 CONTENTS
 - 4.2.1 PURPOSE. The first section of a SOP contains a brief statement explaining the objective of the procedure. It indicates what organization, documentation, and/or activities are involved or affected by the procedure, and a concise background description.
 - 4.2.2 RESPONSIBILITY. The second section of a SOP lists all the functional groups responsible for implementing the procedure or performing the procedures and the duties assigned thereto.
 - 4.2.3 DEFINITION. This section lists the meaning of words or groups of words not commonly known to the potential user of the SOP. For example, technical terms and/or acronyms are described here.
 - 4.2.4 GUIDELINES AND PROCEDURES. This section lists, in detail, all the steps required to perform the particular job task.
 - 4.2.5 REFERENCES. This section lists all the references used in compiling the operating procedure.
- 4.3 FORMAT
 - 4.3.1 CONFORMANCE TO STANDARD. All SOPs drafted must conform with the format set forth in this document.

- 4.3.2 PAGE HEADER CONTENTS. Each page shall include a header containing the Department logo in the upper left corner, and a document identifier in the upper right hand corner that contains the following information in nine (9) point bolded type, Arial:

SOP No.:
Revision No.:
Date:
Page of

- 4.3.3 TYPEFACE. All type, except the header, shall be 11 point, Arial.
- 4.3.4 PAGE MARGINS. Margins will be 1-inch top and bottom and 1-inch left and right.
- 4.3.5 COVERSHEET CONTENTS. Each SOP has a coversheet that contains the following information (see FIGURE 1, appended): (1) operation title; (2) SOP number; (3) revision number; (4) approval sign-off; (5) effective date; and; (6) distribution check-off.
- 4.3.6 DRAFT APPROVAL SHEET. A SOP Draft Approval Sheet (see FIGURE 3, appended) to be utilized to track the review and approval of preliminary drafts of SOPs.
- 4.4.7 SECTIONS. The first level of written division in a SOP document is referred to as a "section". Single digit numbers are used to identify a section. The heading of a section must have the "SOP SECTION HEADING" *character style* applied to it and the text of the section, including its heading must have the "SOP Section Text" *paragraph style* applied to it. By applying these *styles* to the heading and body, each will automatically be formatted and indented to its appropriate position. A tab between the section number and heading activates the hanging indent, and two spaces between header title and any paragraph text are used to separate the heading from the body. (see Figure 2, appended)
- 4.4.8 SUB-SECTIONS. The second level of written division in a SOP document that is part of, but separate from, a section is referred to as a "sub-section". Two numbers, separated by a period, identify a sub-section. The numbers and words in the heading of a sub-section must have the "SOP SUB-SECTION HEADING" *character style* applied to it, and the text of the sub-section, including its heading, must have the "SOP Sub-section Text" *paragraph style* applied to it. By applying these *styles* to the heading and body, each will automatically be formatted and indented to its appropriate position. A tab between the sub-section number and heading activates the hanging indent, and two spaces between end of the header title and beginning of any sub-section text are used to separate the heading from the body. (see FIGURE 2, appended)

- 4.3.9 PARAGRAPHS. The third level of written division in a SOP document that is part of, but separate from, a sub-section is referred to as a "paragraph". Three numbers, separated by periods, identify a paragraph. The numbers and words in the heading of a paragraph must have the "SOP PARAGRAPH HEADING" *character style* applied to it, and the text of the paragraph, including its heading, must have the "SOP Paragraph Text" *paragraph style* applied to it. By applying these *styles* to the heading and body, each will automatically be formatted and indented to its appropriate position. A tab between the paragraph number and heading activates the hanging indent, and two spaces between end of the heading title and beginning of any paragraph text are used to separate the heading from the body. (see FIGURE 2, appended)
- 4.3.10 SUB-PARAGRAPHS. The fourth and final level of written division used in a SOP document is part of, but separate from, a paragraph is referred to as a "sub-paragraph". An uppercase letter enclosed in parentheses identifies a sub-paragraph. The letter and any words in the heading of a sub-paragraph must have the "SOP SUB-PARAGRAPH HEADING" *character style* applied to it, and the text of the sub-paragraph, including its heading, must have the "SOP Sub-paragraph Text" *paragraph style* applied to it. By applying these *styles* to the heading and body, each will automatically be formatted and indented to its appropriate position. A tab between the sub-paragraph letter and heading activates the hanging indent, and two spaces between end of the heading title and beginning of the sub-paragraph text are used to separate the heading from the body. (see FIGURE 2, appended)
- 4.3.11 TABLES AND FIGURES. The inclusion of illustrative tables and figures is appropriate in SOPs. Since the format of these items will vary, no prescribed method is established herein. All tables and figures must be identified with a number and title that will have the "SOP Tables and Figures Id." *paragraph style* applied to it. By applying this *style* to the number and title, it will automatically be formatted and centered to its appropriate position. (see heading of FIGURE 2, appended)
- 4.4 SOP APPROVAL PROCESS. The SOP approval process consists of a preliminary draft cycle and a final approval cycle.
- 4.4.1 PRELIMINARY DRAFT DEVELOPMENT. In the preliminary draft cycle, the originator contacts their Supervisor and Division Director to gain approval for going forward with drafting a proposed SOP. Upon approval to proceed, the originator should work with appropriate staff to prepare a draft.
- 4.4.2 PRELIMINARY DRAFT APPROVAL. The preliminary draft is submitted to the originator's supervisor, Division Director, Bureau Policy and Procedures staff, and Bureau Director for their review and approval. These reviewers should use their judgment to include those individuals

and groups that may be required to comply with the proposed SOP. All reviewers must submit comments to the originator, indicating approval or changes necessary

- 4.4.3 COMMENT RECONCILIATION. The originator of the draft SOP will resolve any issues or objections identified in the draft review cycle. Upon resolution of the comments, the originator must obtain approval signatures on the Draft Approval Routing Sheet from any unit supervisor and Division Director affected by the SOP, as well as the relevant Bureau Policy and Procedures Unit.
- 4.4.4 INTRA-BUREAU APPROVAL. After all comments have been received and appropriately reconciled, the originator will present a version of the reworked draft SOP to their Bureau Director for approval. This version of the SOP will identify language added to the original draft with underlined text and language deleted from the original draft with ~~stricken out text~~. Upon approval by the Bureau Director, they sign the Draft Approval Routing Sheet. Once this has been completed, the draft will be submitted to the SMT for the final approval cycle.
- 4.4.5 SMT AND QMSC APPROVAL. Bureau Directors are responsible for bringing bureau approved SOPs to SMT for approval. Any comments received at this stage will be returned to the originator for reconciliation. The Deputy Commissioner is responsible for signing-off on behalf at the recommendation of the Senior Management Team. The Deputy Commissioner will forward the approved SOP to the QMSC for final disposition.
- 4.4.6 DISTRIBUTION. After all final approval signatures have been obtained, the originator is responsible for distributing the SOP to any affected parties, as evidenced by a completed distribution list on the Coversheet. Policy and procedures staff in each bureau and the QAM are the points of contact for receiving all final SOPs. The current version of each SOP shall be made available in hard copy in a designated location in each bureau and the OC, and on the DEP intranet.
- 4.4.7 LIFE CYCLE MAINTENANCE. Each bureau, and the OC, shall designate a staff member responsible for tracking and maintaining bureau-specific and department-wide SOPs. All SOPs shall be reviewed at least bi-annually, and revised or withdrawn as necessary. Revisers shall assure that all affected parties receive the revised version, and withdraw the earlier. Program managers ensure that staff receive training necessary to carry out changes in procedure documented in revised SOPs, or cease using procedures no longer authorized. Earlier versions and withdrawn procedures shall be archived at the organizational level at which they originated.

FIGURE 1 – SAMPLE COVERSHEET

COVERSHEET
STANDARD OPERATING PROCEDURE

Operation Title:
Identification No.:
Revision No.:
Originator Name:
Effective Date:

APPROVALS:

Bureau Director:

Print Name Signature Date: _____

QMSC Chair:

Print Name Signature Date: _____

Deputy Commissioner on behalf of SMT:

Print Name Signature Date: _____

Other:

Print Name Signature Date: _____

DISTRIBUTION:

() Bureau of Air Quality By: _____ Date: _____
() Bureau of Land and Water Quality By: _____ Date: _____
() Bureau of Remediation and Waste Management By: _____ Date: _____
() Office of the Commissioner By: _____ Date: _____
() Quality Management Steering Committee By: _____ Date: _____

FIGURE 2 – FORMAT SENARIOS

1. SECTION HEADING. Section Text. (see 4.4.2)

1.1 SUB-SECTION HEADING. Subsection text. (see 4.4.3)

1.1.1 PARAGRAPH HEADING. Paragraph text. (see 4.4.4)

(A) SUB-PARAGRAPH HEADING. Sub-paragraph text (see 4.4.5)

FIGURE 3 – DRAFT APPROVAL ROUTING FORM

**DRAFT APPROVAL ROUTING FORM
STANDARD OPERATING PROCEDURE**

Date in Process:

Operation Title:

Identification No.:

Revision No.:

Originator Name:

The attached draft is forwarded for your evaluation and comment. Suggested changes should be concise and reasons specific. Return to sender.

Supervisor:

Print Name

Initials

Date

☐ redraft based on comments ☐ OK

Division Director:

Print Name

Initials

Date

☐ redraft based on comments ☐ OK

Bureau Policy & Procedures:

Print Name

Initials

Date

☐ redraft based on comments ☐ OK

Bureau Director:

Print Name

Initials

Date

☐ redraft based on comments ☐ OK

FIGURE 4 – IDENTIFICATION AND CODING SYSTEM

OFFICE OF THE COMMISSIONER (OC)

OC-BF Budget and Finance
 OC-CU Clerical Unit
 OC-CS Computer Services
 OC-HR Human Resources
 OC-PP Policy and Planning
 OC-PE Procedures and Enforcement
 OC-OIA Office of Innovation and Assistance
 OC-EO Education and Outreach

AIR QUALITY (A)

A-AM Air Monitoring
 A-CU Clerical Unit
 A-DMU Data Management Unit
 A-FS Field Services
 A-LE Licensing and Engineering
 A-PP Policy and Procedures

LAND AND WATER QUALITY (LW)

LW-CU Clerical Unit
 LW-DMU Data Management Unit
 LW-EA Environmental Assessment
 LW-ETA Engineering and Technical Assistance
 LW-PP Policy and Procedures
 LW-LRR Land Resource Regulation
 LW-WRR Water Resource Regulation
 LW-WM Watershed Management

REMEDIATION AND WASTE MANAGEMENT (RWM)

RWM-CU Clerical Unit
 RWM-DMU Data Management Unit
 RWM-HWFR . Hazardous Waste Facilities Regulation
 RWM-PP Policy and Procedures
 RWM-RS Response Services
 RWM-SWFR . Solid Waste Facilities Regulation
 RWM-TS Technical Services

APPENDIX 5:

QUALITY AUDITING SOP

IDENTIFICATION NO.: QMP-001

**COVERSHEET
STANDARD OPERATING PROCEDURE**

Operation Title: **Quality Auditing**
Identification No.: QMP-001
Revision No.: **02**
Originator Name: **David VanWie**
Revisor: Malcolm Burson, for QMSC
Effective Date: 06/01/03

APPROVALS:

QMSC Chair:

		Date: <u> </u>
Print Name	Signature	

Deputy Commissioner on behalf of SMT:

		Date: <u> </u>
Print Name	Signature	

Other:

		Date: <u> </u>
Print Name	Signature	

DISTRIBUTION:

() Bureau of Air Quality	By: <u> </u>	Date: <u> </u>
() Bureau of Land and Water Quality	By: <u> </u>	Date: <u> </u>
() Bureau of Remediation and Waste Management	By: <u> </u>	Date: <u> </u>
() Office of the Commissioner	By: <u> </u>	Date: <u> </u>
() Quality Management Steering Committee	By: <u> </u>	Date: <u> </u>

1. **PURPOSE.** The purpose of this procedure is to ensure an effective auditing program in Maine DEP, including an auditing plan, auditing program, and auditor training.

Audits are conducted at many levels in the Department to determine conformance with Department rules, standard operating procedures (SOPs) and other applicable requirements. Other objectives of audits are to determine the accuracy of data collection and management systems, identify opportunities for program improvements, and to verify the effectiveness of Department programs. Other important benefits of auditing are cross training, assurance that policies and procedures are current and being followed by staff, and continuous improvement.

This procedure is applicable to all program activities defined in the Maine DEP's Quality Management Plan. A bureau or program may specify additional procedures or requirements for conducting audits within that organization. The QMSC and Bureau Directors will identify and prioritize audit issues, develop annual audit plans, and ensure that audits conform to this procedure.

2. DEFINITIONS AND ABBREVIATIONS

- 2.1 **AUDIT PROTOCOLS.** The term *Audit Protocols* refers to written documents, data systems, checklists, procedures or guides that define the audit scope, to assist the auditor with completing the required elements of the audit plan, and to assist the audit area in preparing for the audit.
- 2.2 **AUDIT.** The term *Audit* refers to a systematic and documented verification process to objectively obtain and evaluate evidence to determine whether an organization is in conformance or compliance with legal requirements, internal policies, adopted standards, and defined procedures, and to ensure that necessary corrective actions are made in a timely manner.
- 2.3 **AUDIT TEAM.** The term *Audit Team* refers to at least an audit team leader and other auditors assigned based on complexity and scope of the audit.
- 2.4 **DATA QUALITY ASSESSMENT.** The term *Data Quality Assessment* refers to a specialized audit or portion of an audit focused on data collection, validation, and management according to specified data quality objectives.

3. RESPONSIBILITY

- 3.1 It is the responsibility of Division Directors and program unit managers to implement actions that will ensure conformance with internal policies, adopted standards and defined procedures, and to ensure that necessary corrective action are made in a timely manner.
- 3.2 The QMSC is responsible for management of the audit program, including but not limited to the following functions:

- Approve a general annual auditing plan.
 - Approve (and revise as needed) audit procedures.
 - Receive reports of audit findings and communicate specific findings to appropriate levels of management.
 - Monitor overall implementation of corrective actions from audits.
 - Annually evaluate the audit program (and develop evaluation criteria and methodology).
- 3.3 Bureau Directors are responsible for developing annual audit plans for their Bureaus, and for receiving audit findings, and for ensuring timely implementation of appropriate corrective actions.
- 3.4 It is the responsibility of all employees to be familiar with, participate in and support the Bureau's policies and procedures affecting their work.
- 3.5 It is the responsibility of the audit team leaders to plan, schedule and conduct audits according to the predefined scopes.

4. REQUIREMENTS

4.1 AUDIT TEAM

- 4.1.1 Auditors will be qualified by training and experience, and will follow generally accepted guidelines for auditors.
- 4.1.2 Audits will employ a team approach including, when possible, members from different parts of the organization.
- 4.1.3 MDEP staff will typically perform audits, provided that the auditors' duties and responsibilities are independent of the area and facility being audited.
- 4.1.4 Outside experts may be used on teams when necessary to ensure technical expertise, or necessary independence.

4.2 AUDIT PREPARATION/PLANNING

- 4.2.1 The QMSC will prepare annually an audit plan. Periodic updates and revisions will be made to accommodate revised schedules or priorities as they arise.
- 4.2.2 The plan will include areas and activities to be audited and the expected dates during the upcoming cycle.
- 4.2.3 The plan will identify the audit team, including the team leader, and

- 4.2.4 The plan shall include information about the planned scope and general methodology of each audit.

4.3 AUDIT EXECUTION

- 4.3.1 The Division Director(s) of the area to be audited should be notified of the audit at least 30 days prior to the audit. The notification will include any special areas or issues not addressed in established audit procedures, as well as a pre-audit questionnaire (if appropriate). The Division Director, Program Manager, Bureau QAC, and Lead Auditor will jointly determine the scope and objective(s) of the proposed audit.
- 4.3.2 Prior to the field portion of an audit, a desk or record audit may be performed by the audit team;
- 4.3.3 One week prior to the audit, a final schedule will be agreed upon between the audit team leader and the Division Director(s).
- 4.3.4 The audit team will prepare, in advance, the audit methodology to be used, including checklists, worksheets, interview questions and protocols. The audit plan will be reviewed and approved by the QMSC prior to implementation.
- 4.3.5 The audit team will conduct an Opening Meeting with local management, including the Division Director. The purpose of this meeting will be to review the audit scope, methods, logistics, reporting requirements, Corrective Action Request (CAR) forms, and follow-up requirements.
- 4.3.6 The audit team will use accepted methods to collect and document objective verifiable evidence. This evidence will include, but not be limited, to observations, file review, document review, interviews, testing or inspection.
- 4.3.7 The audit team will conduct a Closing Meeting with the local management, including the Division Director, to outline the major findings of the audit and to clarify any issues. Local management will acknowledge receipt of audit findings, and may indicate disagreement with specific findings. Whenever possible, Corrective Action Requests will be presented and acknowledged at the Closing Meeting.
- 4.3.8 Following the on-site visit, the audit team will meet to review the findings and to document the need for corrective or follow-up action as necessary using Corrective Action Request (CAR) forms.

4.4 AUDIT REPORTING AND CORRECTIVE ACTION FOLLOW-UP

- 4.4.1 An audit report, including CAR forms, will be prepared by the audit team within two weeks of the audit. Copies will be forwarded to the Division

Director(s) for the area that was audited. The Division Director is responsible for distributing the audit report, and assigning responsibilities for Corrective Action to program managers or other responsible staff.

- 4.4.2 Within four weeks of the Closing Meeting, or the receipt of CARs, whichever is later, the Division Director(s) will propose Corrective Actions and a timeline for completion of each, and submit the corrective action plans to the Bureau Director and QMSC. The Division Director may request the assistance of the Lead Auditor to review findings and develop Corrective Actions.
- 4.4.3 Completion of the corrective actions will be monitored by Bureau Director, through the bureau Quality Assurance Coordinator, on a monthly basis. Completed actions will be deleted from the Corrective Action Plan when evidence of completion is provided. Corrective Action Requests and Plans shall be tracked in an on-line database available to all DEP employees.
- 4.4.4 The Lead Auditor is responsible for assuring that all persons interviewed or otherwise involved in the audit receive a copy of the audit report.
- 4.4.5 The QAM is responsible, six months following the completion of the audit, for requesting from the division director(s) receiving CARs a progress report on CAP completion, and soliciting feedback on audit effectiveness. If necessary, the audit team may be asked to conduct a follow-up review of corrective actions to ensure effective implementation.

5. COMMUNICATION AND TRAINING. All auditors will be trained on the contents of this procedure and all applicable auditing standards.

6. EVALUATION. The QMSC will conduct an annual evaluation of the audit program.

References

APPENDIX 6:

QUALITY MANAGEMENT STAFF

QUALITY MANAGEMENT STAFF (May, 2001)

Maine DEP has no position wholly dedicated to QA/QC/QI functions; as detailed in Element 2 of this QMP, our approach to quality management integrates this function throughout the agency rather than concentrating responsibilities in a few individuals. The following list reflects the structure and positions identified in Element 2.1, as well as bureau-level individuals whose job responsibilities have significant quality components.

QUALITY MANAGEMENT STEERING COMMITTEE

NAME	POSITION	ADDRESS	TELEPHONE AND FAX #	EMAIL
Brooke Barnes	Deputy Commissioner, OC	17 State House Station Augusta, Maine 04333	207-287-7887 207-287-2814	Brooke.e.barnes@State.me.us
Malcolm Burson	Director of Special Projects and Quality Assurance Manager, OC	17 State House Station Augusta, Maine 04333	207-287-7755 207-287-2814	Malcolm.c.burson@State.me.us
James Dusch	Director of Enforcement, OC	17 State House Station Augusta, Maine 04333	207-287-8662 207-287-2814	Jim.e.dusch@State.me.us
Andy Johnson	Field Services Environmental Specialist IV, BAQ	17 State House Station Augusta, Maine 04333	207-287-7047 207-287-7641	Andy.johnson@State.me.us
David Maxwell	Director, Division of Program Services, BRWM	17 State House Station Augusta, Maine 04333	207-287-7872 207-287-7826	David.w.maxwell@State.me.us

BUREAU QUALITY MANAGEMENT COORDINATORS

NAME	POSITION	ADDRESS	TELEPHONE AND FAX #	EMAIL
Bryce Sproul	Director, Division of Environmental Services Engineering, Bureau of Air Quality	17 State House Station Augusta, Maine 04333	207-287-7048 207-287-7641	Bryce.j.sproul@State.me.us
David McCaskill	Environmental Engineering Specialist, Bureau of Remediation and Waste Management	17 State House Station Augusta, Maine 04333	207-287-7056 207-287-7826	David.mccaskill@State.me.us
Hetty Richardson	Policy and Procedure Staff, Bureau of Land and Water Quality	17 State House Station Augusta, Maine 04333	207-287-7799 207-287-7191	Hetty.l.richardson@State.me.us

OTHER KEY PERSONNEL

NAME	POSITION	ADDRESS	TELEPHONE AND FAX #	EMAIL
Brian Beneski	Oil and Hazardous Materials Specialist, Remediation Division, BRWM	17 State House Station Augusta, Maine 04333	207-287-7799 207-287-7191	Brian.beneski@State.me.us
Denise Cormier	Field Services Laboratory and QA Support, BAQ	17 State House Station Augusta, Maine 04333	207-287-2451 207-287-7191	Denise.e.cormier@State.me.us
Susan Davies	Senior Biologist and Quality Assurance Coordinator, Division of Environmental Assessment, BLWQ	17 State House Station Augusta, Maine 04333	207-287-7778 207-287-7191	Susan.p.davies@State.me.us
Norm Marcotte	Quality Assurance Coordinator, Division of Watershed Management, BLWQ	17 State House Station Augusta, Maine 04333	207-287-7727 207-287-7826	Norm.g.marcott@State.me.us
Rick Mayo	Environmental Chemist, Field Services Laboratory, BAQ	17 State House Station Augusta, Maine 04333	207-287-3653 207-287-7191	Rick.mayo@State.me.us
Deb Stahler	Senior Chemist and QA Manager, Technical Services Division BRWM	17 State House Station Augusta, Maine 04333	207-287-7878 207-287-7641	debrah.l.stahler@State.me.us

APPENDIX 7:

QMS / R-1(2001)

CONTROL OF DEPARTMENT DOCUMENTS AND RECORDS

Intent: Maine DEP's Quality Management Plan, the ANSI/ASQ E-4 standard on which it is based, and the applicable Federal Assistance regulations require that the organization document the manner in which documents and records are controlled. The standards below should be considered the minimum requirements, and do not preclude DEP bureaus, offices, and program areas from implementing more stringent standards. The standards below provide a fuller description of the quality system requirements outlined in Element 5 (Documents and Records) of Maine DEP's QMP.

Definitions: For purposes of these requirements,

- ◆ *Documents* are all publications and forms, in hard copy and electronic media, which are generated by the Department for use by staff or the public. This category particularly includes internal documents that specify quality-related requirements and instructions, such as QAPPs, SOPs, sampling and analysis plans, etc.
- ◆ *Forms* are a sub-set of documents used to record or compile data. When entries are made on a form, it may become a record.
- ◆ *Records* furnish evidence of activities carried out by the Department and by external entities such as regulated facilities. Any record entered into a file for official purposes (e.g., discharge monitoring report; facility correspondence; payroll vouchers) is considered a public record (1 M.R.S.A. §402 (3))¹. Records may include photographs, drawings, objects, samples, reports, and electronic data.

I. General Requirements

1. Beginning on the date of approval of this document, all Maine DEP bureaus are responsible for planning, documenting, and implementing the procedures and practices needed to bring documents and records under their control into conformance with these standards.
2. Each Bureau shall designate a person responsible for overseeing interpretation and implementation of these guidelines.

II. Control of Documents

1. All DEP documents shall carry, on each page, either the official seal of the Maine DEP and/or the printed name (Maine DEP / Department of Environmental Protection) of the organization. It shall also carry, on each page, an identifiable title that reflects its use, and a page number. On multi-page documents, this information can be presented a less prominent location, and/or in a smaller font, than on the first or title page.

Exceptions:

- (a) Materials produced entirely by another entity (e.g., EPA) but provided to the public by DEP.
 - (b) Multi-page documents providing non-regulatory public information need these data only on the cover page.
 - (c) Web pages intended to provide general information.
 - (d) Reportsmith generated documents.
2. All DEP documents shall carry, in some location on each page, an indication of the date of composition or revision. Bureaus shall determine whether, and which, documents also require a tracking designation unique to the document. Bureaus shall determine whether, and how, to track documents for purposes of assuring the use of the most current revision, identification of author, inventory, etc.

¹ The statutory exceptions to the category of public records would not affect these requirements.

3. Documents, including forms, that are in draft form shall be clearly identified as such, including any restrictions on circulation or use.

III. Control of Forms

Because many forms, when filled in, become public records, the standards of control are more stringent. Thus, in addition to the requirements in (I) above,

1. All DEP forms shall carry a document tracking designation that includes an identification of the issuing bureau; a unique number or alpha-numeric designation; a date of composition or revision; and a revision number.
2. Each bureau shall implement a system to control forms in order to assure that when forms are revised, previous versions are removed from use in a timely manner depending on the significance of the revision, etc.
3. Any form which may become a public record must include, at a minimum, the following fields:
 - (a) Date when the form was used / completed;
 - (b) Record identification (e.g., facility permit number)
 - (c) Name of the person(s) completing the form.

IV. Control of Records

1. All records documenting the activities of entities regulated by Maine DEP, or subject to enforcement actions by Maine DEP, shall be uniquely identified with at least the following information, which may be contained in the body of the record or added separately:
 - (a) The number of the associated permit, license, or enforcement action if one exists;
 - (b) Name and location, or a unique identifier, of the facility or activity recorded;
 - (c) Date of action or activity recorded or documented in the record;
 - (d) Date of receipt of the record;
 - (e) Name of the DEP employee responsible for the record.

This standard shall apply to records created by outside entities when received for use by Maine DEP. This category of record includes correspondence, including electronic mail, initiated or received by Maine DEP, and any filed copies of the same.

2. Each bureau shall determine the level of identification and control applicable to other records, whether public records or not. Records for which a unique identifier cannot readily be created must be stored in such a manner that any particular record can be found on request.

APPENDIX 8

PROGRAMS AND TECHNICAL ACTIVITIES INVOLVING **ENVIRONMENTAL DATA OPERATIONS**

(internal and extramural)

Summary of Programs with Environmental Data Operations

Bureau of Air Quality:

- Ambient Air Quality Monitoring – Field Operations
- Ambient Air Quality Monitoring – Laboratory Operations
- Meteorological Modeling
- Emissions Inventory – Criteria Pollutants
- Emissions Inventory – Air Toxics
- Compliance
- Enforcement
- Licensing
- Rule Making
- State Implementation Plan Development
- Small Business Technical Assistance
- Mobile Sources

Bureau of Land and Water Quality:

- Technical Assistance and Compliance
- Pollution Prevention and Technical Assistance
- State Revolving Loan Fund (SRF)
- Combined Sewer Overflow (CSO)
- Biological Monitoring
- Data Management
- Hydrogeology
- Lakes
- Invasive Plants
- Marine Waters
- Rivers
- Dioxin Monitoring
- Surface Water Ambient Toxics Monitoring (SWAT)
- Excavation and Quarry Notification
- Natural Resource Protection
- Shoreland Zoning
- Site Location of Development
- Stormwater Management (and Erosion and Sediment Control)
- Municipal/Industrial Licensing
- Hydropower Licensing
- Overboard Discharge Licensing
- Marine Pump-Out
- Underground Injection Control

- DWRR Enforcement
- Nonpoint Source
- Nonpoint Source Training Center
- Technical Assistance
- Watershed Planning
- NOAA Coastal Zone Management

Bureau of Remediation and Waste Management:

- Resource Conservation and Recovery Act (C) – hazardous wastes
- Resource Conservation and Recovery Act (I) – underground storage tanks
- Toxic Substances Control Act – Asbestos
- Toxic Substances Control Act – Lead
- Toxic Substances Control Act – PCB
- Leaking Underground Storage Tanks Trust
- Superfund (multiple subprograms)
- Department of Defense Federal Facilities Projects

Programs and Technical Activities Involving Environmental Data Operations Contracted or Delegated by Maine DEP (examples)

Note: May be included in activities of any of the above program areas.

- Self-monitoring activities by permitted entities, *e.g.*, water treatment facilities delegated under NPDES
- Activities carried out under the terms of assistance agreements, *e.g.*, Soil and Water Conservation Districts; Volunteer Lakes Monitoring Program
- Data in support of permit application provided by a contractor, *e.g.*, wetlands delineation carried out with the guidance of a Federal SOP
- Sampling and monitoring operations as part of contracted site remediation activities.